FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Selection Criteria:

Product Name:	VEKLURY			
Product Active Ingredient:				
Active Ingredient:	REMDESIVIR			
Active Moiety:				
FDA Received Date:	From:	01-Jan-2020	To:	03-Nov-2020
MedDRA® Version* :	23.1			
Total Cases**:	3829			
Number of Pages:	1527			

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

*. "MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

**. "Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.

The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting. Direct: submitted "directly" to FDA by healthcare professionals, patients and other consumers.
Health Prof	Indicates whether the initial source who provided information about the event is a health professional. Possible values are; Y - Yes, N – No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Mfr Control #	The Manufacturer Control Number is the manufacturer's unique identifier associated with the case. Also referred to as the Company Report Number.
503B Facility	Indicates whether the organization that sent the report to FDA is an outsourcing facility. An outsourcing facility is a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the Food, Drug, and Cosmetic Act. Possible value is Y – Yes.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).

Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to "code" adverse events, medication errors and other information associated with the use of medical products.
Product	Name of a drug or biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Comp.	Indicates whether the suspect product is a compounded drug, as identified in the report. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Possible value is Y – Yes.
OTC	Indicates whether the suspect product is an over-the-counter (OTC) drug, as identified in the report. OTC drug products are those drugs that are available to consumers without a prescription. Possible value is Y – Yes.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Mfr	The manufacturer of the product, as indicated in the report.

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678768	EXPEDITED (15-DAY)		DE, LT, OT	US-ABBVIE-20K-163-3367450-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure; Septic Shock	Nimbex			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Enoxaparin			S	Subcutaneous			Not Reported
	Cefepime			S	Intravenous (not otherwise specified)			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Lispro Insulin			S	Subcutaneous			Not Reported
	Lispro Insulin			S				Not Reported
	Lispro Insulin			S				Not Reported
	Lantus			S	Subcutaneous			Not Reported
	Lantus			S	Subcutaneous			Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)			Not Reported
	Famotidin			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Levophed			S	Unknown			Not Reported
	Propofol			S	Intravenous (not otherwise specified)			Not Reported
	Albumin			S	Unknown			Not Reported
	Digoxin			S	Unknown			Not Reported
	Sodium Bicarbonate			S	Unknown			Not Reported
	Lipitor			C				Not Reported
	Tessalon			C				Not Reported
	Ceftriaxone			C				Not Reported

	Doxycycline			C					Not Reported
	Lopressor			C					Not Reported
	Kayexalate			C					Not Reported
	Fentanyl			C					Not Reported
	Diltiazem			C					Not Reported
	Norepinephrine			C					Not Reported
	Gabapentin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686488	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-019093		64 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Hypersensitivity; Off Label Use; Rash Maculo-Papular	Piperacillin+Tazobactam			S	Intravenous drip	13 Gram, Once A Day		Aurobindo
	Remdesivir			S	Intravenous drip	100 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17694433	EXPEDITED (15-DAY)		HO	US-ALLERGAN-2015860US			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Norco 2.5/325			S	Unknown	Unk		Allergan
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Ribavirin			C		Unk		Not Reported
	Docusate Sodium			C		Unk		Not Reported
	Escitalopram			C		Unk		Not Reported

	Heparin	C	Unk	Not Reported
	Levothyroxine	C	Unk	Not Reported
	Lorazepam	C	Unk	Not Reported
	Magnesium Sulfate	C	Unk	Not Reported
	Potassium Chloride	C	Unk	Not Reported
	Alprazolam	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731692	NON-EXPEDITED		OT	US-SA-2020SA110743			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aspartate Aminotransferase Increased; Blood Calcium Decreased; Blood Potassium Decreased; Gastrointestinal Haemorrhage	Lovenox			S	Subcutaneous	100 Mg, Bid		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Eliquis			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Dexmedetomidine			C	Unknown	Unk		Not Reported
	Apixaban			C	Unknown	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Docusate Sodium			C	Unknown	Unk		Not Reported
	Fluticasone Furoate;Vilanterol			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Hydrocodone			C	Unknown	Unk		Not Reported
	Insulin Aspart			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Loratadine			C	Unknown	Unk		Not Reported
	Polyethylene Glycol			C	Unknown	Unk		Not Reported

	Prednisone	C	Unknown	Unk		Not Reported
	Sertraline	C	Unknown	Unk		Not Reported
	Inula Helenium Root;Senna Alexandrina Leaf	C		Unk		Not Reported
	Quetiapine	C		Unk		Not Reported
	Propofol	C		Unk		Not Reported
	Pantoprazole	C		Unk		Not Reported
	Multivitaminum	C		Unk		Not Reported
	Hydromorphone	C		Unk		Not Reported
	Enoxaparin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	17746673	EXPEDITED (15-DAY)		DE, OT	US-SA-2020SA114426			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Fenofibrate			C	Unknown	Unk		Not Reported
	Heparin			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported
	Nph Insulin			C	Unknown	Unk		Not Reported
	Humuline			C	Unknown	Unk		Not Reported
	Sodium Chloride			C	Unknown	Unk		Not Reported
	Sitagliptin			C	Unknown	Unk		Not Reported
	Midazolam			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2020	18261812	DIRECT					40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)		10 DAY 10 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	18246617	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17770443	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hyperhidrosis; Hypotension; Infusion Related Reaction; Infusion Site Reaction; Nausea; Vomiting	Remdesivir	Y		S	Intravenous drip		30 MIN	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2020	17770487	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Disease Progression; Hypertension; Oxygen	Remdesivir	Y		S	Intravenous drip			Not Reported

Saturation Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17770490	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endotracheal Intubation	Remdesivir			S				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17770498	DIRECT	Y	DE			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Pulseless Electrical Activity; Ventricular Fibrillation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17770540	DIRECT	Y	OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17770559	DIRECT	Y				79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770551	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Allopurinol			C				Not Reported
	Aspirin			C				Not Reported
	Digoxin			C				Not Reported
	Famotidine			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17774804	DIRECT	Y	HO			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17774838	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardio-Respiratory Arrest; Dialysis; Pneumonia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17774848	DIRECT	Y	HO			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Blood Creatinine Increased; Oliguria	Remdesivir	S	Intravenous drip	Gilead
	Vancomycin	C		Not Reported
	Potassium Chloride	C		Not Reported
	Etomidate	C		Not Reported
	Succinylcholine	C		Not Reported
	Fentanyl	C		Not Reported
	Naloxone	C		Not Reported
	Piperacillin/Tazobactam	C		Not Reported
	Norepinephrine	C		Not Reported
	Inhaled Epoprostenol	C		Not Reported
	Famotidine	C		Not Reported
	Aspirin Chewable	C		Not Reported
	Bisacodyl Suppository	C		Not Reported
	Gabapentin	C		Not Reported
	Insulin Lispro	C		Not Reported
	Propofol	C		Not Reported
	Senna	C		Not Reported
	Iv Furosemide 40 Mg X 1	C		Not Reported
	Hydroxychloroquine Or Placebo	C		Not Reported
	Enoxaparin	C		Not Reported
	Heparin	C		Not Reported
	Metolazone 10 Mg	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17774850	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Covid-19 Pneumonia; Haemodynamic Instability; Hypotension; Renal Tubular Necrosis; Respiratory Failure; Weight Decreased	Remdesivir			S	Intravenous drip			Gilead
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Diazepam			C				Not Reported
	Docusate			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Heparin 7,500 Units Sq			C				Not Reported
	Insulin Lispro			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Quetiapine			C				Not Reported

	Propofol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17774851	DIRECT	Y	HO			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir	Y		S	Intravenous drip		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17775263	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Product Label Confusion	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17776492	DIRECT	Y				76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Thrombocytopenia	Remdesivir			S				Not Reported
	Aspirin			C				Not Reported
	Amlodipine			C				Not Reported
	Cholecalciferol			C				Not Reported
	Torsemide			C				Not Reported
	Enoxaparin			C				Not Reported
	Levothyroxine			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17781018	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir	S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17781025	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Chest X-Ray Abnormal; Clinical Trial Participant; Oxygen Consumption Increased; Product Use In Unapproved Indication; White Blood Cell Count Increased	Remdesivir			S				Not Reported
	Fentanyl			C				Not Reported
	Hydralazine			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Pantoprazole			C				Not Reported
	Enoxaparin			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784372	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Diarrhoea; Nausea; Product Use In Unapproved Indication; Vomiting	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Finasteride			C				Not Reported
	Gabapentin			C				Not Reported
	Guaifenesin/Codeine			C				Not Reported
	Heparin			C				Not Reported
	Lisinopril			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Propranolol			C				Not Reported
	Saline Nasal Spray			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Combivent Respimat			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17790333	DIRECT	Y				71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chills; Clinical Trial Participant; Electrocardiogram Change; Hypotension; Infusion Related Reaction; Mental Status Changes; Nausea; Product Use In Unapproved Indication; Pulse Abnormal	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17790340	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Clinical Trial Participant; Product Use In Unapproved Indication; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17790341	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Product Label Confusion; Product Preparation Error	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Furosemide			S	Intravenous bolus			Not Reported
	Bumetanide			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Docusate			C				Not Reported
	Epoprostenol Inhalation			C				Not Reported
	Etomidate			C				Not Reported

		Fentanyl			C					Not Reported
		Gabapentin			C					Not Reported
		Lorazepam			C					Not Reported
		Maraviroc			C					Not Reported
		Methylprednisolone			C					Not Reported
		Midazolam			C					Not Reported
		Norepinephrine			C					Not Reported
		Propofol			C					Not Reported
		Vasopressin			C					Not Reported
		Vecuronium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17791132	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500mg			C				Not Reported
	Atorvastatin 20mg Tab			C				Not Reported
	Azithromycin 500mg Iv			C				Not Reported
	Ceftriaxone 1gm Iv Daily			C				Not Reported
	Cholecalciferol 4,000 Units Daily			C				Not Reported
	Doxycycline 100mg Iv Q12h			C				Not Reported
	Enoxaparin 40mg Daily			C				Not Reported
	Furosemide 20mg Once			C				Not Reported
	Hydroxychloroquine 400mg			C				Not Reported
	Irbesartan 75mg Daily			C				Not Reported
	Potassium 20meq Once			C				Not Reported
	Zinc Sulfate 440mg Daily			C				Not Reported
	Acetaminophen 650mg Q4h Prn			C				Not Reported
	Fentanyl 50mcg Q2h Prn			C				Not Reported
	Dexmedetomidine Infusion			C				Not Reported
	Heparin Infusion			C				Not Reported
	Insulin Lispro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792090	EXPEDITED (15-DAY)		OT	CH-SA-2020SA124099		61 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dermatitis Exfoliative Generalised; Eosinophilia; Rash Erythematous	Ceftriaxone	S		Not Reported
	Clarithromycin	S	Unk	Not Reported
	Azithromycin	S	Unk	Not Reported
	Amlodipine (Salt Not Specified)	S	5 Mg	Not Reported
	Oxazepam	S	Unk	Not Reported
	Lasix	S	Unk	Sanofi
	Lasix	S	Unk	Sanofi
	Lasix	S	Unk	Sanofi
	Clexane	S	40 Mg	Sanofi
	Clexane	S	40 Mg	Sanofi
	Lorazepam	S	Unk	Not Reported
	Paracetamol	S	Unk	Not Reported
	Paracetamol	S	Unk	Not Reported
	Quetiapine Fumarate	S	Unk	Not Reported
	Esomeprazole Magnesium	S	Unk	Not Reported
	Esomeprazole Magnesium	S	Unk	Not Reported
	Haldol	S	Unk	Not Reported
	Remdesivir	S	Unk	Not Reported
	Diamox [Acetazolamide]	C	Unk	Not Reported
	Diamox [Acetazolamide]	C	Unk	Not Reported
	Diamox [Acetazolamide]	C	Unk	Not Reported
	Distraneurin	C		Not Reported
	Heparine	C	Unk	Not Reported
	Novorapid	C		Not Reported
	Ipramol	C	Unk	Not Reported
	Lexotanil	C	Unk	Not Reported
	Movicol	C	Unk	Not Reported
	Morphine	C	Unk	Not Reported
	Nozinan	C	Unk	Not Reported
	Antibiotics For Otic And Nasal Use	C	Unk	Not Reported

Antibiotics For Otic And Nasal Use	C	Unk	Not Reported
Antibiotics For Otic And Nasal Use	C	Unk	Not Reported
Solu-Medrol	C	Unk	Not Reported
Dexdor	C	Unk	Not Reported
Dexdor	C	Unk	Not Reported
Dexdor	C	Unk	Not Reported
Sintenyl	C	Unk	Not Reported
Sintenyl	C	Unk	Not Reported
Dormicum	C	Unk	Not Reported
Dormicum	C	Unk	Not Reported
Dormicum	C	Unk	Not Reported
Noradrenaline	C	Unk	Not Reported
Noradrenaline	C	Unk	Not Reported
Noradrenaline	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Rocuronium	C	Unk	Not Reported
Tracrium	C		Not Reported
Tracrium	C	Unk	Not Reported
Tracrium	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792126	DIRECT	Y	DE			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792128	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hypotension; Infusion Related Reaction	Remdesivir			S	Intravenous drip	Other Frequency:X1 (Loading Dose);		Gilead
	Apap 500 Mg Po Q6hr Prn Pain/Fever			C				Not Reported
	Ascorbic Acid 1500 Mg Po Daily			C				Not Reported
	Cefepime 1 G Ivpb Q12hr			C				Not Reported
	L-Thyroxine 175 Mcg Po Daily			C				Not Reported
	Lorazepam 0.5 Mg Po Tid Prn Anxiety			C				Not Reported
	Ondansetron 4 Mg Iv Push Q6hr Prn N/V			C				Not Reported
	Vancomycin 1.5 G Ivpb Q12hr			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792132	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Refusal Of Treatment By Relative	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792142	DIRECT	Y	HO			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17792175	DIRECT	Y	HO			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794224	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0467265		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Covid-19 Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797263	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poor Quality Product Administered; Product Storage Error	Remdesivir	Y		S	Intravenous (not otherwise specified)		6 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797264	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Blood Creatinine Increased; Fluid Overload	Remdesivir			S	Intravenous drip			Gilead
	Cefepime			C				Not Reported
	Lactobacillus			C				Not Reported
	Aspirin			C				Not Reported
	Fentanyl Continuous Drip			C				Not Reported

	Dextometomedine			C						Not Reported
	Propofol			C						Not Reported
	Heparin Subcutaneous			C						Not Reported
	Famotidine			C						Not Reported
	Methylpredinosolone			C						Not Reported
	Humalog			C						Not Reported
	Humulin Nph			C						Not Reported
	Venelex			C						Not Reported
	Ocean Mist			C						Not Reported
	Refresh			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797623	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hypotension	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797878	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797266	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Remdesivir			S	Intravenous bolus			Gilead
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin			C				Not Reported
	Melatonin			C				Not Reported
	Methylprednislone			C				Not Reported

		Zinc			C						Not Reported
		Fentanyl			C						Not Reported
		Norepinephrine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797267	DIRECT	Y	OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead
	Convalescent Plasma For Covid-19			C				Not Reported
	Tocilizumab Or Placebo/Covacta Study			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797268	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Coronary Artery Stenosis; Depressed Level Of Consciousness; Hemiparesis; Mental Status Changes; Renal Ischaemia	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma For Covid-19			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797269	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Function Test Abnormal	Remdesivir			S	Intravenous drip			Gilead
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797270	DIRECT	Y				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased; Therapy Interrupted	Remdesivir			S				Not Reported
	Benzonatate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Clonazepam			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Methylprednisolone			C				Not Reported
	Omeprazole			C				Not Reported
	Ropinirole			C				Not Reported
	Topiramate			C				Not Reported
	Ziprasidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797271	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797281	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797285	DIRECT	Y				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Increased; Hypertension; Therapy Change	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Digoxin			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Hydralazine			C				Not Reported
	Losartan			C				Not Reported
	Methylprednisolone			C				Not Reported
	Nebivolol			C				Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797292	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Protein Total Increased; Renal Tubular Necrosis; Sepsis	Remdesivir			S	Intravenous drip	Other Frequency:Once, Then 100mg;		Gilead
	Heparin/Enoxaparin Subcutaneous			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Insulin Lispro			C				Not Reported
	Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported
	Levothyroxine 150 Mcg			C				Not Reported
	Tocilizumab 400 Mg			C				Not Reported
	Ethacrynic Acid			C				Not Reported
	Metoprolol			C				Not Reported
	Tradipitant			C				Not Reported
	Trimethobenzamide 200 Mg Injection			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17798027	DIRECT	Y	RI			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Remdesivir (Gs-5734)	Y	S	Intravenous (not otherwise specified)		Gilead
	Remdesivir (Gs-5734)	Y	S	Intravenous (not otherwise specified)		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17798044	DIRECT	Y	HO			60 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Coagulopathy; Organ Failure; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17801712	DIRECT	Y	OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798196	DIRECT	Y	OT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Therapy Cessation	Remdesivir 200 Mg			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Dextromethorphan			C				Not Reported
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported

		Aspirin			C					Not Reported
		Ibuprofen			C					Not Reported
		Vitamin C			C					Not Reported
		Zinc Sulfate			C					Not Reported
		Hydroxychloroquine			C					Not Reported
		Prednisone			C					Not Reported
		Albuterol Hfa			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798574	DIRECT	Y	OT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Therapy Cessation	Remdesivir 200 Mg			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Dextromethorphan			C				Not Reported
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Aspirin			C				Not Reported
	Ibuprofen			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Prednisone			C				Not Reported
	Albuterol Hfa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801700	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801703	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801706	DIRECT	Y	DE, LT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; General Physical Health Deterioration; Oxygen Saturation Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)		3 DAY	Gilead
	Cefepime 2g Iv Q12h			C				Not Reported
	Ascorbic Acid 1500mg Iv Q6h			C				Not Reported
	Thiamine 200mg Iv Q12h			C				Not Reported
	Doxycycline 100mg Po Bid			C				Not Reported
	Methylprednisolone 60mg Iv Q12h			C				Not Reported
	Pantoprazole 20mg Po Q24h			C				Not Reported
	Sertraline 100mg Po Q24h			C				Not Reported
	Methylprednisolone 60mg Iv Q24h			C				Not Reported
	Tamsulosin 0.4mg Po Q24h			C				Not Reported
	Zinc Capsule 50mg Po Q24h			C				Not Reported
	Ipratropium Inh 2 Puffs Po Q6h			C				Not Reported
	Enoxaparin 30mg Sc Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801710	DIRECT	Y	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive; Vomiting	Remdesivir			S	Intravenous drip			Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Glargine			C				Not Reported
	Ondansetron			C				Not Reported
	Oxycodone			C				Not Reported
	Prochloroperazine			C				Not Reported
	Ceftriaxone			C				Not Reported

	Doxycycline			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801711	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801746	DIRECT	Y	OT			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Hypotension; Respiratory Failure; Tachypnoea; Urine Output Decreased; White Blood Cell Disorder	Remdesivir			S				Gilead
	Vancomycin			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801755	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Liver Function Test Increased; Product Use In Unapproved Indication; Renal Replacement Therapy	Remdesivir			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801760	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Differential White Blood Cell Count Abnormal; Leukopenia; Lymphocyte Percentage Increased; Neutrophil Percentage Decreased; Product Use In Unapproved Indication	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 1500mg Po Bid			C				Not Reported
	Cholecalciferol 50mcg Po Q24h			C				Not Reported
	Zinc Capsule 50mg Po Q24h			C				Not Reported
	Magnesium Oxide 420mg Po Bid			C				Not Reported
	Insulin Glargine 12 Units Sc Qhs			C				Not Reported
	Insulin Aspart Sliding Scale Tid Ac			C				Not Reported
	Senna 17.2mg Po Daily			C				Not Reported
	Enoxaparin 30mg Sc Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801796	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Hydroxychloroquine Or Matching Placebo			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801801	DIRECT	Y	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypovolaemia; Renal Tubular Necrosis	Remdesivir Injection (For Use Under Eua)			S	Intravenous drip			Gilead
	Remdesivir Injection (For Use Under Eua)			S	Intravenous drip			Gilead
	Vancomycin 2g Iv Q12			C				Not Reported

		Vancomycin 1g Iv Q12			C					Not Reported
		Vancomycin 1g Iv X 1			C					Not Reported
		Enoxaparin			C					Not Reported
		Famotidine			C					Not Reported
		Pregabalin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801805	DIRECT	Y	OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous bolus	Other Frequency:200mg X 1 100mg X4;		Gilead
	Cefepime			C				Not Reported
	Methylprednisolone			C				Not Reported
	Azithromycin			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Furosemide			C				Not Reported
	Carvedilol			C				Not Reported
	Docusate			C				Not Reported
	Folic Acid			C				Not Reported
	Neurontin			C				Not Reported
	Clopidogrel			C				Not Reported
	Pantoprazole			C				Not Reported
	Mvi			C				Not Reported
	Heparin Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801809	DIRECT	Y	HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydrocortisone			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported

		Piperacillin-Tazobactam			C						Not Reported
		Polyethylene Glycol 3350			C						Not Reported
		Vancomycin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801815	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Swelling; Throat Irritation	Remdesivir	Y		S				Not Reported
	Amlopidine			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Lisinopril			C				Not Reported
	Nystatin Oral Susp			C				Not Reported
	Percocet			C				Not Reported
	Pantoprazole			C				Not Reported
	Sitagliptin			C				Not Reported
	Zinc			C				Not Reported
	Vitamin D			C				Not Reported
	Vitamin C			C				Not Reported
	Aspirin			C				Not Reported
	Metformin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Dipridamole			C				Not Reported
	Empagliflozin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Letrozole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801819	DIRECT	Y	HO			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Discomfort; Infusion Related Reaction; Nausea; Vomiting	Remdesivir			S	Intravenous drip	Other Frequency:Once;	20 MIN	Gilead
	Albuterol Inhaler			C				Not Reported
	Atorvastatin			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Lisinopril			C				Not Reported
	Pantoprazole			C				Not Reported

		Tiotropium			C					Not Reported
		Norco 5			C					Not Reported
		Tussionex			C					Not Reported
		Ondansetron			C					Not Reported
		Prochlorperazine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801824	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Remdesivir			S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported
	Zinc			C				Not Reported
	Quetiapine			C				Not Reported
	Methylprednisolone			C				Not Reported
	Melatonin			C				Not Reported
	Levetiracetam			C				Not Reported
	Atorvastatin			C				Not Reported
	Ascorbic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801829	DIRECT	Y	HO			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Hypoxia	Remdesivir			S	Intravenous bolus			Gilead
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801885	DIRECT	Y	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Body	Remdesivir			S	Intravenous (not	Other Frequency:Once;		Gilead

Temperature Increased; Heart Rate Increased; Hyperhidrosis; Nausea; Oxygen Saturation Decreased; Respiratory Rate Increased	otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801892	DIRECT	Y	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Ceftriaxone			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Azithromycin			C				Not Reported
	Tocilizumab			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801899	DIRECT	Y				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Dose Omission In Error	Remdesivir			S	Intravenous bolus			Gilead
	Tocilizumab 760mg			C				Not Reported
	Convalescent Serum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801905	DIRECT	Y	HO			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead

	Remdesivir	Y	S	Intravenous bolus		Gilead
	Cosyntropin		C			Not Reported
	Cefepime		C			Not Reported
	Melatonin		C			Not Reported
	Hydrocortisone Sodium Succinate		C			Not Reported
	Mercaptopurine		C			Not Reported
	Azithromycin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801912	DIRECT	Y	LT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Azotaemia; Continuous Haemodiafiltration; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17802626	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Covid-19; Dyspnoea; General Physical Health Deterioration; Hypotension; Liver Function Test Abnormal; Multiple Organ Dysfunction Syndrome; Oxygen Saturation Decreased; Pneumonia Staphylococcal; Pyrexia; Renal Function Test Abnormal; Sars-Cov-2 Test Positive	Covid-19 Convalescent Plasma			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Versiti Blood Centers
	Remdesivir			S				Not Reported
	Dapsone			C				Not Reported
	Linezolid			C				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802614	DIRECT	Y	LT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802618	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Continuous Haemodiafiltration; Inadequate Haemodialysis; Renal Impairment	Remdesivir			S	Intravenous drip		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802638	DIRECT	Y	DE			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Cardiac Arrest; Covid-19; Disease Complication; Pneumonia Pseudomonal; Respiratory Failure	Remdesivir			S	Intravenous bolus			Gilead
	Amiodarone			C				Not Reported
	Amlodipine			C				Not Reported
	Carvedilol			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lactobacillus Acidophilus			C				Not Reported
	Lansoprazole			C				Not Reported
	Lorazepam			C				Not Reported
	Meropenem			C				Not Reported
	Metoclopramide			C				Not Reported

		Multivitamin			C						Not Reported
		Oxycodone			C						Not Reported
		Polyethylene Glycol 3350			C						Not Reported
		Potassium Chloride			C						Not Reported
		Neutra-Phos			C						Not Reported
		Senna			C						Not Reported
		Vancomycin			C						Not Reported
		Hydromorphone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802944	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Hydroxychloroquine Or Matching Placebo (Orchid Trial)			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802952	DIRECT	Y	DE			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Leviteracetam			C				Not Reported
	Oxcarbazepine			C				Not Reported
	Amlodipine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Lispro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805154	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0466529		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chills; Hypotension; Nausea	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806590	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Amolodipine			C				Not Reported
	Atracurium			C				Not Reported
	Carvedilol			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Lidocaine Patch			C				Not Reported
	Midazolam			C				Not Reported
	Multivitamin			C				Not Reported
	Acetaminophen			C				Not Reported
	Atracurium			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806639	DIRECT	Y	LT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Haemodynamic Instability; Pneumothorax; Pulmonary Embolism; Sepsis; Shock	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806644	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Remdesivir	Y	S	Intravenous bolus	Gilead
	Bisacodyl Suppository		C		Not Reported
	Bumetanide 1mg Inj		C		Not Reported
	Ceftriaxone 2g Inj		C		Not Reported
	Chlorhexidine 0.12% Swish		C		Not Reported
	Enoxaparin 100mg		C		Not Reported
	Fentanyl 100mcg/Hr		C		Not Reported
	Ipratropium-Albuterol Neb		C		Not Reported
	Lactated Ringer Infusion		C		Not Reported
	Potassium Phosphate 15mmol Bolus		C		Not Reported
	Propfol Infusion 40mcg/Kg/Min		C		Not Reported
	Rocuronium 10m/Ml Infusion		C		Not Reported
	Vancomycin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806653	DIRECT	Y	LT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Foetal Heart Rate Abnormal; Haemodynamic Instability; Respiratory Failure	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806658	DIRECT	Y	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Condition Aggravated; Haemodialysis	Remdesivir Eua			S				Not Reported
	Amlodipine 5mg			C				Not Reported
	Ascorbic Acid 1000mg			C				Not Reported
	Ceftriaxone 1g			C				Not Reported
	Doxycycline 100mg			C				Not Reported
	Furisemide 40mg			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806695	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Creatinine Increased; Body Temperature Increased; Infusion Related Reaction	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Apixaban			C				Not Reported
	Doxazosin			C				Not Reported
	Hydralazine			C				Not Reported
	Lorazepam			C				Not Reported
	Combivent Respimat			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Levothyroxine			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806699	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Septic Shock	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Norepinephrine			C				Not Reported
	Cisatracurium			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806709	DIRECT	Y	RI			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806721	DIRECT	Y	DE, LT, OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Fluid Overload; Hypoxia; Respiratory Disorder; Shock	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Bensonatate			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Normosol-R			C				Not Reported
	Enoxaparin			C				Not Reported
	Epinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Iopamidol			C				Not Reported
	Lactated Ringers			C				Not Reported
	Lorazepam			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Melatonin			C				Not Reported
	Metaclopramide			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Morphine			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806725	DIRECT	Y	DE, OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Cardiac Arrest; Hypernatraemia; Metabolic Acidosis; Paralysis; Respiratory Acidosis; Respiratory	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexmedetomide Drip			C				Not Reported
	Enoxaparin 100 Mg Subq Q12h			C				Not Reported
	Insulin			C				Not Reported
	Methylprednisolone 60 Mg Iv			C				Not Reported

Failure	Q12h								
	Lorazepam 2 Mg Iv Q4h Prn			C					Not Reported
	Levophed Infusion			C					Not Reported
	Methylprednisolone 40 Mg Iv Q12h			C					Not Reported
	Dopamine Infusion			C					Not Reported
	Epinephrine Infusion			C					Not Reported
	Phenylephrine Infusion			C					Not Reported
	Epoprostenol For Inhalation			C					Not Reported
	Sodium Bicarb 150 Meq/Swi 1l At 150 Ml/Hr			C					Not Reported
	Vancomycin			C					Not Reported
	Piperacillin/Tazobactam			C					Not Reported
	Heparin Low Intensity Infusion			C					Not Reported
	Amiodarone Iv			C					Not Reported
	Ketamine Infusion			C					Not Reported
	Morphine Infusion			C					Not Reported
	Rocuronium Infusion			C					Not Reported
	Tocilizumab 800 Mg Iv X1 Dose			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806729	DIRECT	Y	DE			92 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806734	DIRECT	Y	DE			96 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Abnormal; Renal Failure; Respiratory Failure	Remdesivir Eua			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500 Mg			C				Not Reported
	Cefepime 1 Gram			C				Not Reported
	Ergocalciferol 50,000 Units			C				Not Reported
	Hydromorphone 0.2 Mg Iv			C				Not Reported
	Methylprednisolone 40 Mg			C				Not Reported

	Injection			
	Pantoprazole 40 Mg Tablet	C		Not Reported
	Senna 17.2 Mg	C		Not Reported
	Sodium Chloride 0.9% Neb	C		Not Reported
	Zinc Sulfate 220 Mg	C		Not Reported
	Mirtazapine 7.5 Mg	C		Not Reported
	Morphine 4 Mg/Ml Injection	C		Not Reported
	Torsemide 20 Mg	C		Not Reported
	Norepinephrine 8 Mg / 250 Ml	C		Not Reported
	Vancomycin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806736	DIRECT	Y	DE			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Clinical Trial Participant; Product Use In Unapproved Indication; Pulseless Electrical Activity; Tachycardia	Remdesivir Eua	Y		S				Not Reported
	Amikacin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Vasopressin			C				Not Reported
	Cefepime			C				Not Reported
	Cholecalciferol			C				Not Reported
	Diphenhydramine			C				Not Reported
	Docusate			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Robitussin Dm			C				Not Reported
	Insulin Lispro			C				Not Reported
	Tocilizumab			C				Not Reported
	Melatonin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Midazolam			C				Not Reported
	Montelukast			C				Not Reported
	Pantoprazole			C				Not Reported
	Vancomycin			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806739	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Clinical Trial Participant; Product Use In Unapproved Indication; Sepsis; Shock; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806745	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806790	DIRECT	Y	OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Blood Pressure Decreased; Body Temperature Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Desvenlafaxine			C				Not Reported
	Epoetin Alfa			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone Sodium Succinate			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported

			Methadone			C					Not Reported
			Metoprolol			C					Not Reported
			Potassium Chloride			C					Not Reported
			Pregabalin			C					Not Reported
			Azithromycin			C					Not Reported
			Hydroxychloroquine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17807091	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17807562	DIRECT	Y	RI			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Creatinine Increased; Blood Pressure Systolic Increased; Glomerular Filtration Rate Decreased; Increased Bronchial Secretion; Oxygen Saturation Decreased; Po2 Decreased	Remdesivir 100 Mg/20 Ml Iv (Eua Drug)			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Apap			C				Not Reported
	Ca/Vit D			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Quetiapine			C				Not Reported
	Morphine			C				Not Reported
	Pravastatin			C				Not Reported
	Ezetimibe			C				Not Reported
	Fluoxetine			C				Not Reported
	Memantine			C				Not Reported
	Rivaroxaban			C				Not Reported
	Docusate			C				Not Reported
	Famotidine			C				Not Reported
	Calcitonin			C				Not Reported
	Kcl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17807632	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir (Euc) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807338	DIRECT	Y				8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Product Formulation Administered; Product Use Issue	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807340	DIRECT					62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Pneumomediastinum	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807341	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807897	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir 200mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg	Y		S				Gilead
	Remdesivir 100mg	Y		S				Gilead
	Hydromorphone			C				Not Reported
	Acetaminophen			C				Not Reported
	Zofran			C				Not Reported
	Vitd3			C				Not Reported
	Titralac			C				Not Reported
	Seroquel			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Lasix			C				Not Reported
	Lovenox			C				Not Reported
	Miralax			C				Not Reported
	Benadryl			C				Not Reported
	Levophed			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Potassium Chloride			C				Not Reported
	Clozaril			C				Not Reported
	Propofol			C				Not Reported
	Amidate			C				Not Reported
	Quellcin			C				Not Reported
	Fantanyl			C				Not Reported
	Versed			C				Not Reported
	Humulin			C				Not Reported
	Humalog			C				Not Reported
	Ancef			C				Not Reported
	Protonix			C				Not Reported
	Flagyl			C				Not Reported
	Rocephin			C				Not Reported
	Vancomycin			C				Not Reported
	Zenpep			C				Not Reported
	Prilosec			C				Not Reported
	Potassium Bicarbonate			C				Not Reported
	Zemuron			C				Not Reported
	Convalescent Plasm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810951	DIRECT	Y				58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810957	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810962	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased	Remdesivir Iv	Y		S	Intravenous drip			Gilead
	Insulin Aspart Sliding Scale			C				Not Reported
	Metoprolol Injection			C				Not Reported
	Cisatracurium Injection			C				Not Reported
	Norepinephrine Injection			C				Not Reported
	Propofol Injection			C				Not Reported
	Fentanyl Injection			C				Not Reported
	Vasopressin Injection			C				Not Reported
	Vancomycin Injection			C				Not Reported
	Cefepime Injection			C				Not Reported
	Enoxaparin Injection			C				Not Reported
	Pantoprazole Injection			C				Not Reported
	Tocilizumab Injection			C				Not Reported
	Digoxin Injection			C				Not Reported
	Melatonin Tablet			C				Not Reported
	Aspirin 325mg Tablet			C				Not Reported
	Furosemide Injection			C				Not Reported
	Metolazone Tablet			C				Not Reported
	Insulin Glargine			C				Not Reported

	Atorvastatin Tablet			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810969	DIRECT	Y	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810975	DIRECT	Y	HO, OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir Remdesivir			S C				Gilead Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810977	DIRECT	Y	OT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemofiltration	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Stat Dose;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810978	DIRECT	Y				77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased;	Remdesivir			S	Intravenous drip			Gilead

Haemofiltration	Tocilizumab			C						Not Reported
	Linezolid			C						Not Reported
	Enoxaparin			C						Not Reported
	Vitamin C			C						Not Reported
	Thiamine			C						Not Reported
	Pepcid			C						Not Reported
	Zinc			C						Not Reported
	Precedex			C						Not Reported
	Fentanyl			C						Not Reported
	Propofol			C						Not Reported
	Rocuronium			C						Not Reported
	Cisatracurium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810988	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Renal Injury	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810994	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Infusion Related Reaction	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811012	DIRECT	Y	OT			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Impairment; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amlodipine 10 Mg Daily			C				Not Reported
	Ascorbic Acid 500 Mg Po Bid			C				Not Reported
	Aspirin 81 Mg Po Daily			C				Not Reported

	Ceftriaxone 1g Iv Daily	C		Not Reported
	Dextrose 5% Iv, 100 Ml/Hr	C		Not Reported
	Diphenhydramine 25 Mg Iv X 1	C		Not Reported
	Doxycycline 100 Mg Po Bid	C		Not Reported
	Doxycycline Suspension 100 Mg Po Bid	C		Not Reported
	Enoxaparin 40 Mg Sq Bid	C		Not Reported
	Famotidine 20 Mg Bid	C		Not Reported
	Fentanyl Iv Infusion	C		Not Reported
	Furosemide Iv 20 Mg X1 Then 40 Mg Bid	C		Not Reported
	Hydralazine 10 Mg Iv Q4h Prn	C		Not Reported
	Regular Insulin Infusion	C		Not Reported
	Insulin Glargine	C		Not Reported
	Insulin Lispro	C		Not Reported
	Ketamine Infusion	C		Not Reported
	Methylprednisolone Iv	C		Not Reported
	Montelukast	C		Not Reported
	Ondansetron	C		Not Reported
	Tocilizumab Iv	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811020	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Cefazolin			C				Not Reported
	Cisatricurium			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lansoprazole			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Vancomycin			C				Not Reported

		Vecuronium			C					Not Reported
		Angiotensin Ii			C					Not Reported
		Hydromorphone			C					Not Reported
		Fentanyl			C					Not Reported
		Midazolam			C					Not Reported
		Norepinephrine			C					Not Reported
		Vasopressin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811029	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Melatonin			C				Not Reported
	Nebivolol			C				Not Reported
	Valsartan			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811036	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Blood Creatinine Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811043	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Glomerular Filtration Rate Decreased; Therapy Interrupted	Remdesivir	S	Intravenous bolus		Gilead
	Amlodipine	C			Not Reported
	Cefepime	C			Not Reported
	Enoxaparin	C			Not Reported
	Insulin Aspart	C			Not Reported
	Insulin Detemir	C			Not Reported
	Duo-Neb	C			Not Reported
	Linezolid	C			Not Reported
	Morphine	C			Not Reported
	Pantoprazole	C			Not Reported
	Acetaminophen	C			Not Reported
	Fentanyl	C			Not Reported
	Midazolam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811050	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Respiratory Failure; Septic Shock; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811056	DIRECT	Y	OT			71 YR	Male	AFG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Remdesivir	Y		S	Intravenous drip			Gilead
	Flomax			C				Not Reported
	Vitamin C 1000mg			C				Not Reported
	Zinc 220			C				Not Reported
	Allopurinol 300mg			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Ceftriazone 1gm			C				Not Reported
	Dipyridamole			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Glargine			C				Not Reported

		Insulin Lispro			C					Not Reported
		Zestorectic			C					Not Reported
		Meropenem			C					Not Reported
		Methylprednisolone			C					Not Reported
		Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811063	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811080	DIRECT	Y	DE			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Fibrillation	Remdesivir	Y		S	Intravenous bolus			Gilead
	Albumin 5% 25g			C				Not Reported
	Bumetanide 1mg Q12h			C				Not Reported
	Calcium 500mg With Vit D 5mcg 2 Daily			C				Not Reported
	Ceftriaxone 2g Iv Daily			C				Not Reported
	Enoxaparin 80mg Bid			C				Not Reported
	Furosemide 20mg Once			C				Not Reported
	Norepinephrine 4mg/250ml Infusion			C				Not Reported
	Oxycodone 5mg Q6h			C				Not Reported
	Pantoprazole 40mg Q12h			C				Not Reported
	Propofol Infusion 25mcg/Kg/Min			C				Not Reported
	Psyllium 58.6% Packet			C				Not Reported
	Ribavirin 600mg Q8h			C				Not Reported
	Sertraline 150mg Daily			C				Not Reported
	Vitamin D 2000 Units Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811088	DIRECT	Y	OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Haemofiltration; Liver Function Test Increased; Renal Impairment; Right Ventricular Dysfunction	Remdesivir Via Emergency Use Authorization			S	Intravenous drip			Not Reported
	Covid-19 Convalescent Plasma			C				Not Reported
	Tocilizumab 400 Mg Iv In 100 Ml Nacl			C				Not Reported
	Tocilizumab 400 Mg Iv In 100 Ml Nacl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811092	DIRECT	Y	HO, LT, OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Erythema; Rash Macular	Remdesivir			S				Gilead
	Acetaminophen			C				Not Reported
	Morphine			C				Not Reported
	Vancomycin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Tocilizumab Or Placebo			C				Not Reported
	Furosemide			C				Not Reported
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811136	DIRECT	Y	DS, HO, LT, OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Movement Disorder; Hypoxia; Lung Infiltration; Miosis; Pyrexia; Respiratory Distress; Tachycardia; Unresponsive To Stimuli;	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen 650mg Po Q4h Prn			C				Not Reported
	Azithromycin 500mg Po Daily			C				Not Reported
	Enoxaparin 40mg Subq Daily			C				Not Reported
	Famotidine 20mg Po Daily			C				Not Reported

Unresponsive To Stimuli	Ondansetron 4mg Iv Q6h Prn	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811139	DIRECT	Y	HO, LT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased; Respiratory Distress	Remdesivir			S				Gilead
	Albuterol			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Aspirin Ec			C				Not Reported
	Doxycycline			C				Not Reported
	Atorvastatin			C				Not Reported
	Pyridostigmine			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Acetaminophen			C				Not Reported
	Zinc			C				Not Reported
	Ondansetron			C				Not Reported
	Diphenhydramine			C				Not Reported
	Amiodarone			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811147	DIRECT	Y	DS, HO, LT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carotid Artery Occlusion; Ischaemic Stroke	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Hydroxychloroquine Or Placebo			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Potassium Bicarbonate			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811158	DIRECT	Y	DE			60 YR	Male	ALB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Oxygen Saturation Decreased	Remdesivir			S		Other Frequency:Loading Dose;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17812033	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Rash; Tachycardia	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812217	DIRECT	Y	DE			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hypertension; Hypotension; Multiple Organ Dysfunction Syndrome; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812224	DIRECT	Y	DE			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Lung Disorder; Pulmonary Embolism; Sudden Death	Remdesivir			S	Intravenous bolus			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812243	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Sarilumab			C				Not Reported
	Apixaban			C				Not Reported
	Furosemide			C				Not Reported
	Polyetheylene Glycol			C				Not Reported
	Sennosides			C				Not Reported
	Bisacodyl			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Hydralazine			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Docusate			C				Not Reported
	Metoprolol			C				Not Reported
	Ropinorole			C				Not Reported
	Tamsulosin			C				Not Reported
	Carbidopa/Levodopa			C				Not Reported
	Losartan			C				Not Reported
	Paroxetine			C				Not Reported
	Finasteride			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812244	DIRECT	Y	DE			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Morphine Pca			C				Not Reported
	Levetiracetam			C				Not Reported
	Enoxaparin			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Folic Acid			C				Not Reported

	Finasteride	C		Not Reported
	Terazosin	C		Not Reported
	Pantoprazole	C		Not Reported
	Aspirin	C		Not Reported
	Atorvastatin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812245	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812248	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poor Quality Product Administered; Product Storage Error	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812559	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Hypotension; Vomiting	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Precedex			C				Not Reported
	Diltiazem			C				Not Reported
	Docusate			C				Not Reported
	Duloxetine			C				Not Reported
	Enoxaparin			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Furosemide			C				Not Reported
	Haloperidol			C				Not Reported

		Hydralazine			C					Not Reported
		Lantus			C					Not Reported
		Insulin Lispro			C					Not Reported
		Lactobacillus			C					Not Reported
		Lorazepam			C					Not Reported
		Magnesium Oxide			C					Not Reported
		Methylprednisolone			C					Not Reported
		Potassium Chloride			C					Not Reported
		Lyrica			C					Not Reported
		Seroquel			C					Not Reported
		Terazosin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812562	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812592	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Zosyn			C				Not Reported
	Levophed			C				Not Reported
	Sinemet			C				Not Reported
	Dilaudid			C				Not Reported
	Methylprednisolone			C				Not Reported
	Actemra			C				Not Reported
	Vancomcyin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812596	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Supraventricular Tachycardia	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812599	DIRECT	Y				39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Throat Irritation	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813534	EXPEDITED (15-DAY)			US-GILEAD-2020-0467788		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Malfunction; Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17815405	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17815427	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Condition Aggravated	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:X1 Then100mg Q24h;	5 DAY	Not Reported
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported

	Apixaban	C	Not Reported
	Aspirin (Enteric Coated) 81 Mg Daily	C	Not Reported
	Atorvastatin	C	Not Reported
	Benztropine	C	Not Reported
	Carvedilol	C	Not Reported
	Divalproex	C	Not Reported
	Famotidine	C	Not Reported
	Guaifenesin + Codeine Prn	C	Not Reported
	Tamsulosin	C	Not Reported
	Insulin Glargine	C	Not Reported
	Insulin, Regular (Sliding Scale)	C	Not Reported
	Ipratropium And Albuterol Inhalation	C	Not Reported
	Loratadine	C	Not Reported
	Methylprednisolone Sodium Succinate	C	Not Reported
	Montelukast	C	Not Reported
	Morphine, Intravenous (Prn)	C	Not Reported
	Ibrutinib	C	Not Reported
	Pantoprazole	C	Not Reported
	Quetiapine (And I Ran Out Of Room: Zosyn)	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17815613	DIRECT	Y	RI			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Dialysis	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17763474	EXPEDITED (15-DAY)		HO	US-ROCHE-2594510		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Unknown			Not Reported

Increased; Deep Vein Thrombosis; Intentional Product Use Issue; Off Label Use	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Enoxaparin	C			Not Reported
	Oxygen	C			Not Reported
	Loperamide	C			Not Reported
	Lovenox [Enoxaparin Sodium]	C			Not Reported
	Zosyn	C			Not Reported
	Tylenol	C			Not Reported
	Vancomycin	C			Not Reported
	Zithromax	C			Not Reported
	Calcium Gluconate	C			Not Reported
	Potassium Chloride	C			Not Reported
	Cholecalciferol	C			Not Reported
	Melatonin	C			Not Reported
	Multivitamin And Mineral	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815622	DIRECT	Y	DE			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Pulseless Electrical Activity; Respiratory Failure	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported
	Diltiazem			C				Not Reported
	Enoxaparin			C				Not Reported
	Lorazepam			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sodium Chloride 0.9% Iv Solution			C				Not Reported
	Hydralazine			C				Not Reported
	Morphine			C				Not Reported
	Vecuronium			C				Not Reported
	Epinephrine Drip			C				Not Reported
	Phenylephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported
	Sodium Bicarbonate Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815629	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Dialysis	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Duoneb			C				Not Reported
	Pantoprazole			C				Not Reported
	Sodium Chloride 0.9% Iv Solution			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815634	DIRECT	Y	OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Intravascular Coagulation; General Physical Health Deterioration; Hypotension; Hypothermia; Infusion Related Reaction	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Duoneb			C				Not Reported
	Pantoprazole			C				Not Reported
	Valacyclovir			C				Not Reported
	Acetaminophen			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815658	DIRECT	Y	DE			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney	Remdesivir			S	Intravenous bolus			Gilead

Injury; Blood Lactic Acid Increased; Cardio-Respiratory Arrest; Haemoglobin Decreased; Hypotension; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815906	DIRECT		DE, HO			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Disseminated Intravascular Coagulation; Hypoxia; Paralysis; Renal Failure; Shock	Remdesivir			S				Not Reported
	Naloxone			C				Not Reported
	Norepinephrine			C				Not Reported
	Inhaled Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported
	Aspirin Chewable			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Lasix			C				Not Reported
	Enoxaparin			C				Not Reported
	Heparin			C				Not Reported
	Metolazone			C				Not Reported
	Etomidate			C				Not Reported
	Succinylcholine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816199	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Product Dispensing Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Albuterol Nebulizer			C				Not Reported
	Carvedilol			C				Not Reported
	Cefepime			C				Not Reported
	Furosemide			C				Not Reported

Heparin	C		Not Reported
Hydrocortisone	C		Not Reported
Norepinephrine	C		Not Reported
Vancomycin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816200	DIRECT	Y	DE			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Prolactin Increased; Cardiac Failure Congestive; Lung Disorder; Oxygen Saturation Decreased	Remdesivir Under Emergency Use Authorization (Eua			S	Intravenous (not otherwise specified)		4 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816201	DIRECT	Y	DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Dialysis; Metabolic Acidosis; Pneumonia Viral	Remdesivir Under Emergency Use Authorization (Eua)			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816202	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not			Gilead

					otherwise specified)			
	Cefepime			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin 40 Mg Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816203	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Remdesivir Eua			S				Not Reported
	Doxycycline			C				Not Reported
	Zosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816204	DIRECT	Y	HO			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Disease Progression	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816205	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Impairment	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Acetaminophen-Hydrocodone			C				Not Reported
	Albuterol-Ipratropium			C				Not Reported
	Apixaban			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Baclofen			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Midazolam			C				Not Reported
	Ferrous Sulfate			C				Not Reported

		Fluconazole			C					Not Reported
		Fluconazole			C					Not Reported
		Folic Acid			C					Not Reported
		Furosemide			C					Not Reported
		Heparin			C					Not Reported
		Meropenem			C					Not Reported
		Tocilizumab			C					Not Reported
		Vancomycin			C					Not Reported
		Norepinephrine			C					Not Reported
		Propfol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816206	DIRECT	Y	LT, OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once Once Load;	5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816207	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Metoprolol			C				Not Reported
	Albuterol 2 Mg/5ml Syrup			C				Not Reported
	Cholecalciferol			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Acetaminophen			C				Not Reported
	Risperidone			C				Not Reported
	Mirtazipine			C				Not Reported
	Trazodone			C				Not Reported
	Risperidone			C				Not Reported
	Rosuvastatin			C				Not Reported
	Rivaroxaban			C				Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816208	DIRECT		HO			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816211	DIRECT	Y				78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Hallucination, Visual; Intensive Care Unit Delirium	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Lorazepam Iv 0.25 Mg			C				Not Reported
	Gabapentin 100 Mg			C				Not Reported
	Requip 1 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816477	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other F		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816490	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Desc;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816502	DIRECT	Y	OT			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Sars-Cov-2 Test Positive	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816556	DIRECT	Y	HO, OT			84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Covid-19	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin			C				Not Reported
	Diltiazem			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Insulin			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Lorazepam			C				Not Reported
	Fentanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816562	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816575	DIRECT	Y	HO			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood	Remdesivir	Y		S	Intravenous drip			Gilead
	Furosemide 40 Mg Iv			C				Not Reported

Creatinine Increased; Renal Impairment; Septic Shock	Norepinephrine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816997	DIRECT	Y	HO			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Haemodialysis	Remdesivir Solution For Injection			S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Acetaminophen			C				Not Reported
	Nicotine Patch			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817002	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication; Renal Replacement Therapy; Respiratory Failure; Shock	Remdesivir Under Emergency Use Authorization (Eua).			S	Intravenous (not otherwise specified)			Gilead
	Fentanyl Infusion			C				Not Reported
	Insulin Regular (Humulin R) Sliding Scale			C				Not Reported
	Propofol Infusion			C				Not Reported
	Enoxaparin (Lovenox)			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Glargine			C				Not Reported
	Norepinephrine (Levophed)			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817004	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clinical Trial Participant; Hepatic Enzyme Increased; Product Use In Unapproved Indication	Remdesivir	S	Intravenous (not otherwise specified)		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818831	EXPEDITED (15-DAY)		DE	US-GILEAD-2020-0468218		96 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17819757	DIRECT	Y	RI			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication; Renal Replacement Therapy	Remdesivir (Eua) 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir (Eua) 100 Mgvial	Y		S	Intravenous (not otherwise specified)	Every 24 Hr		Gilead
	Norepinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Albumin			C				Not Reported
	Azithromycin			C				Not Reported
	Bumetanide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Clonazepam			C				Not Reported
	Desmopressin			C				Not Reported
	Docusate			C				Not Reported
	Dopamine			C				Not Reported
	Enoxaparin			C				Not Reported
	Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Hydromorphone			C				Not Reported

	Ketamine			C					Not Reported
	Insulin			C					Not Reported
	Midodrine			C					Not Reported
	Phenylephrine			C					Not Reported
	Propofol			C					Not Reported
	Rocuronium			C					Not Reported
	Sennosides			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17822985	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous drip			Gilead
	Norepinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17822988	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir Injection	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17822990	DIRECT	Y	OT			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased;	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

Therapy Cessation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17822997	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Continuous Haemodiafiltration; Respiratory Failure; Thrombosis In Device; Urine Output Decreased	Remdesivir			S	Intravenous bolus	Other Frequency:Once, Then;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Tocilizumab Or Placebo Trial			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17823220	DIRECT	Y	RI			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury	Remdesivir (Eua) 100 Mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir (Eua) 100 Mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Albumin			C				Not Reported
	Albuterol			C				Not Reported
	Bumetanide			C				Not Reported
	Caffeine Citrate			C				Not Reported
	Chlorothiazide			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Regular			C				Not Reported
	Lactulose			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Methylprednisolone			C				Not Reported
	Metolazone			C				Not Reported

	Midazolam	C		Not Reported
	Midodrine	C		Not Reported
	Oxycodone	C		Not Reported
	Piperacillin/Tazobactam	C		Not Reported
	Potassium Chloride	C		Not Reported
	Quetiapine	C		Not Reported
	Rocuronium	C		Not Reported
	Vancomycin	C		Not Reported
	Dexmedetomidine	C		Not Reported
	Epoprostenol	C		Not Reported
	Heparin	C		Not Reported
	Hydromorphone	C		Not Reported
	Ketamine	C		Not Reported
	Norepinephrine	C		Not Reported
	Propofol	C		Not Reported
	Vasopressin	C		Not Reported
	Acetaminophen	C		Not Reported
	Fentanyl	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17822998	DIRECT	Y				50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Hypoaesthesia; Pruritus	Remdesivir Eua	Y		S	Intravenous drip			Gilead
	Ceftriaxone (Rocephin) 1,000 Mg In 0.9 % Sodium Chloride (Ns) 50 Ml Ad			C				Not Reported
	Enoxaparin (Lovenox) (Conc: 40 Mg/ 0.4 Ml) Injection 40 Mg			C				Not Reported
	Benzonatate (Tessalon Perles) Capsule 100 Mg			C				Not Reported
	Dextromethorphan-Guaifenesin (Conc: 10-100 Mg/5 Ml) (Robitussin Dm) Sy			C				Not Reported
	Ondansetron (Zofran) (Conc: 2 Mg/Ml) Injection 4 Mg			C				Not Reported
	Polyethylene Glycol 3350 (Miralax) Packet 17 G			C				Not Reported
	Promethazine (Phenergan) 6.25 Mg In 0.9 % Sodium Chloride			C				Not Reported

	(Ns) 50 Ml I									
	Sennosides-Docusate Sodium (8.6-50 Mg/Tab) (Senna Plus) Tablet 2 Table				C					Not Reported
	Simvastatin (Zocor) Tablet 40 Mg				C					Not Reported
	Tramadol (Ultram) Tablet 50 Mg				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823000	DIRECT	Y	OT			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pain	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823003	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospice Care	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823009	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atracurium			C				Not Reported
	Midazolam			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823018	DIRECT	Y	HO, OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir Injection			S	Intravenous drip			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823020	DIRECT	Y	LT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hyperkalaemia	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823021	DIRECT	Y	DE, DS			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823024	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (5 Mg/Ml Injection Concentrate)			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ascorbic Acid 500 Mg Tab			C				Not Reported
	Azithromycin 500 Mg Ivpb			C				Not Reported
	Benzonatate 100 Mg Cap			C				Not Reported
	Ceftriaxone 1 Gm Ivpb			C				Not Reported
	Enoxaparin Inj			C				Not Reported
	Methylprednisolone 40 Mg Iv			C				Not Reported
	Zinc Sulfate 220 Mg Cap			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823028	DIRECT	Y	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Nephropathy Toxic	Remdesivir	Y		S	Intravenous bolus	Other Frequency:X1;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823098	DIRECT	Y	LT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Dialysis; Gastrointestinal Haemorrhage; Glomerular Filtration Rate Decreased; Hepatic Failure; Hyperkalaemia; Hypovolaemic Shock; Metabolic Acidosis; Renal Failure; Shock Haemorrhagic	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Diltiazem			C				Not Reported
	Insulin Lispro			C				Not Reported
	Methylprednisolone			C				Not Reported
	Protonix			C				Not Reported
	Atarax			C				Not Reported
	Lovenox			C				Not Reported
	Ativan			C				Not Reported
	Fentanyl			C				Not Reported
	Versed			C				Not Reported
	Ketamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823103	DIRECT	Y	LT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatine Increased; Dialysis; Gastrointestinal Haemorrhage; Glomerular Filtration Rate Decreased; Hepatic Failure;	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Diltiazem			C				Not Reported
	Insulin Lispro			C				Not Reported
	Methylprednisolone			C				Not Reported

Hypovolaemic Shock; Liver Function Test Increased; Shock Haemorrhagic	Protonix			C						Not Reported
	Atarax			C						Not Reported
	Lovenox			C						Not Reported
	Ativan			C						Not Reported
	Ketamine			C						Not Reported
	Versed			C						Not Reported
	Ativan			C						Not Reported
	Fentanyl			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823031	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Plavix			C				Not Reported
	Lovenox			C				Not Reported
	Fentanyl			C				Not Reported
	Hydralazine			C				Not Reported
	Humalog			C				Not Reported
	Levophed			C				Not Reported
	Omeprazole			C				Not Reported
	Propofol			C				Not Reported
	Humulin			C				Not Reported
	Ativan			C				Not Reported
	Versed			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Vecuronium			C				Not Reported
	Keppra			C				Not Reported
	Solumedrol			C				Not Reported
	Tylenol			C				Not Reported
	Melatonin			C				Not Reported
	Nitroglycerin			C				Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823035	DIRECT	Y				31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Enzyme Increased	Eua Remdesivir	Y		S	Intravenous (not otherwise specified)					Not Reported
	Lovenox			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823037	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823040	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone			C				Not Reported
	Insulin Regular			C				Not Reported
	Lactulose			C				Not Reported
	Levothyroxine			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
	Quetiapine			C				Not Reported
	Senna			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823060	DIRECT	Y	OT			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypotension	Remdesivir	S	Intravenous drip	Other Frequency:Once Then 100 Mgx4;	30 MIN	Gilead
	Bisoprolol 5 Mg	C				Not Reported
	Diltiazem Er 30 Mg	C				Not Reported
	Hydralazine 25 Mg	C				Not Reported
	Losartan 100 Mg	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823067	DIRECT	Y	DE			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Disorder	Covid-19 Convalescent Plasma			S	Intravenous (not otherwise specified)	Other Frequency:2 Units Given Once;		Versiti Blood Centers
	Remdesivir (Eua)			S				Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823073	DIRECT	Y	HO			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823078	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			C				Not Reported
	Fentanyl			C				Not Reported
	Methylprednisolone			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Regular			C				Not Reported

	Vancomycin			C					Not Reported
	Daptomycin			C					Not Reported
	Labetalol			C					Not Reported
	Duoneb Nebulizer			C					Not Reported
	Atorvastatin			C					Not Reported
	Bupropion			C					Not Reported
	Cefepime			C					Not Reported
	Cisatracurium			C					Not Reported
	Dexmedetomidine			C					Not Reported
	Enoxaparin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823118	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Heparin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Propofol			C				Not Reported
	Selinexor			C				Not Reported
	Senna			C				Not Reported
	Trazodone			C				Not Reported
	Zinc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2020	17823125	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Decreased; Renal Injury; Respiratory Rate Increased; Septic Shock; Tachypnoea; Urinary Casts	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Apixaban 5 Mg			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Vasopressin Infusion			C				Not Reported

			Cisatracurium Infusion		C				Not Reported
			Propofol Infusion		C				Not Reported
			Fentanyl Infusion		C				Not Reported
			Tocilizumab 400 Mg		C				Not Reported
			Unfractionated Intravenous Heparin		C				Not Reported
			Piperacillin/Tazobactam 4.5 Grams Q6h		C				Not Reported
			Vancomycin 1250 Mg Q12h		C				Not Reported
			Tradipitant/Placebo		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17820923	EXPEDITED (15-DAY)		DE, OT	US-SA-2020SA130868			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Fenofibrate			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Nph Insulin			C		Unk		Not Reported
	Insulin Human;Insulin Human Injection, Isophane			C		Unk		Not Reported
	Sodium Chloride			C		Unk		Not Reported
	Sitagliptin			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823157	DIRECT	Y	OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous drip				Gilead
	Albuterol Hfa 90mcg/Puff			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823162	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Not Reported
	Zosyn			C				Not Reported
	Doxycyline			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823167	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip			Gilead
	Hydroxychloroquine			C				Not Reported
	Propofol			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823171	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823177	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823181	DIRECT	Y	OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypopnoea; Infusion Related Reaction; Rash; Rash Pruritic; Respiratory Distress; Wheezing	Remdesivir			S				Not Reported
	Allopurinol 100 Mg Tablet			C				Not Reported
	Carvedilol 12.5 Mg Tablet			C				Not Reported
	Enoxaparin 40 Mg Subcutaneous			C				Not Reported
	Famotidine 20mg Tablets			C				Not Reported
	Insulin Glargine Subcutaneous			C				Not Reported
	Insulin Lispro Subcutaneous			C				Not Reported
	Multivitamin Oral Tablet			C				Not Reported
	Polyethylene Glycol 17 G Packet			C				Not Reported
	Senna-Docusate 8.6 Mg-50 Mg Tablet			C				Not Reported
	Tamoxifen 20 Mg Tablets			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823188	DIRECT	Y				60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Albuterol Inhaler			C				Not Reported
	Amlodipine 5 Mg Tablet			C				Not Reported
	Benzonatate 200mg Capsules			C				Not Reported
	Docusate 100 Mg Capsule			C				Not Reported
	Senna Tablets			C				Not Reported
	Enoxaparin 40 Mg Subcutaneous			C				Not Reported
	Famotidine 20mg Tablets			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro Subcutaneous			C				Not Reported
	Levothyroxine 50mcg Tablet			C				Not Reported
	Rosuvastatin 20 Mg Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823195	DIRECT	Y	DE			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Encephalopathy; Hypoxia; Respiratory Distress; Respiratory Failure; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Zosyn			C				Not Reported
	Insulin Lispro & Insulin Glargine			C				Not Reported
	Albuterol			C				Not Reported
	Combivent			C				Not Reported
	Amlodipine			C				Not Reported
	Precedex			C				Not Reported
	Lovenox			C				Not Reported
	Gabapentin			C				Not Reported
	Seebri			C				Not Reported
	Levothyroxine			C				Not Reported
	Ativan			C				Not Reported
	Lopressor			C				Not Reported
	Dulera			C				Not Reported
	Percocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823212	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17823217	DIRECT	Y				89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Administration Site Extravasation	Remdesivir			S	Intravenous drip		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17792758	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2020191603		61 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised; Eosinophilia; Rash Erythematous	Nexium			S	Unknown	Unk		Unknown
	Nexium			S	Unknown	Unk		Unknown
	Temesta (Lorazepam)			S	Unknown	Unk		Pfizer
	Zithromax			S	Unknown	Unk		Pfizer
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Haldol			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Lasix [Furosemide Sodium]			S	Unknown	Unk		Not Reported
	Lasix [Furosemide Sodium]			S	Unknown	Unk		Not Reported
	Lasix [Furosemide Sodium]			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Clarithromycine			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported
	Anxiolit			S	Unknown	Unk		Not Reported
	Clexane			S	Unknown	40 Mg		Not Reported
	Clexane			S	Unknown	40 Mg		Not Reported
	Dafalgan			S	Unknown	Unk		Not Reported
	Dafalgan			S	Unknown	Unk		Not Reported
	Solu-Medrol			C	Unknown	Unk		Not Reported
	Diamox [Acetazolamide]			C	Unknown	Unk		Not Reported
	Diamox [Acetazolamide]			C	Unknown	Unk		Not Reported
	Diamox [Acetazolamide]			C	Unknown	Unk		Not Reported
	Distraneurin [Clomethiazole]			C	Unknown	Unk		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Ipramol			C	Unknown	Unk		Not Reported

Heparine [Heparin Sodium]	C	Unknown	Unk	Not Reported
Lexotanil	C	Unknown	Unk	Not Reported
Movicol [Macrogol 3350; Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C	Unknown	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Nozinan [Levomepromazine Hydrochloride]	C	Unknown	Unk	Not Reported
Dexdor	C	Unknown	Unk	Not Reported
Dexdor	C	Unknown	Unk	Not Reported
Dexdor	C	Unknown	Unk	Not Reported
Sintenyl	C	Unknown	Unk	Not Reported
Sintenyl	C	Unknown	Unk	Not Reported
Dormicum [Midazolam Maleate]	C	Unknown	Unk	Not Reported
Dormicum [Midazolam Maleate]	C	Unknown	Unk	Not Reported
Dormicum [Midazolam Maleate]	C	Unknown	Unk	Not Reported
Noradrenaline [Norepinephrine]	C	Unknown	Unk	Not Reported
Noradrenaline [Norepinephrine]	C	Unknown	Unk	Not Reported
Noradrenaline [Norepinephrine]	C	Unknown	Unk	Not Reported
Propofol	C	Unknown	Unk	Not Reported
Propofol	C	Unknown	Unk	Not Reported
Propofol	C	Unknown	Unk	Not Reported
Propofol	C	Unknown	Unk	Not Reported
Rocuronium [Rocuronium Bromide]	C	Unknown	Unk	Not Reported
Tracrium	C	Unknown	Unk	Not Reported
Tracrium	C	Unknown	Unk	Not Reported
Tracrium	C	Unknown	Unk	Not Reported
Colistin	C	Unknown	Unk	Not Reported
Colistin	C	Unknown	Unk	Not Reported
Colistin	C	Unknown	Unk	Not Reported

Tobramycin	C	Unk		Not Reported
Tobramycin	C	Unk		Not Reported
Tobramycin	C	Unk		Not Reported
Amphotericin B	C	Unk		Not Reported
Amphotericin B	C	Unk		Not Reported
Amphotericin B	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17822479	EXPEDITED (15-DAY)		OT	DE-ABBVIE-20K-062-3416492-00			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Liver Disorder; Multiple Organ Dysfunction Syndrome; Renal Failure	Kaletra			S	Oral			Not Reported
	Remdesivir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823907	DIRECT	Y	OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Dyspnoea	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17823998	DIRECT	Y	DE			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824003	DIRECT	Y	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824009	DIRECT	Y	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Amiodarone 360 Mg/200 Ml			C				Not Reported
	Milrinone 20 Mg/100 Ml			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824025	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Pneumonia; Renal Failure	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824060	DIRECT	Y	DE			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Total;		Gilead
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Methocarbamol			C				Not Reported

	Methylprednisolone Sodium			C					Not Reported
	Midazolam			C					Not Reported
	Norepinephrine			C					Not Reported
	Pregabalin			C					Not Reported
	Propofol			C					Not Reported
	Vancomycin			C					Not Reported
	Vasopressin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824081	DIRECT	Y				38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetylcysteine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Ceftaroline			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Regular			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Senna			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824084	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Acetylcysteine			C				Not Reported
	Atorvastatin			C				Not Reported
	Citalopram			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported

		Protonix			C					Not Reported
		Tiotropium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824086	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Albuterol Ipratropium			C				Not Reported
	Famotidine			C				Not Reported
	Sennosides			C				Not Reported
	Docusate			C				Not Reported
	Insulin Lispro			C				Not Reported
	Epoprostenol			C				Not Reported
	Asprin			C				Not Reported
	Acetaminophen			C				Not Reported
	Norepinephrine			C				Not Reported
	Heparin Drip			C				Not Reported
	Methylprednisone			C				Not Reported
	Midodrine			C				Not Reported
	Ampicillin Sulbactam			C				Not Reported
	Metolazone			C				Not Reported
	Ketamine Drip			C				Not Reported
	Hydromorphone Drip			C				Not Reported
	Cisatracurium Drip			C				Not Reported
	Furosemide			C				Not Reported
	Potassium			C				Not Reported
	Acetazolamide			C				Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824087	DIRECT	Y	HO, OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Burning Sensation; Clinical Trial Participant; Condition Aggravated;	Remdesivir			S				Gilead

Covid-19 Pneumonia; Product Use In Unapproved Indication; Respiratory Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824088	DIRECT	Y				85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Decreased Appetite; Product Use In Unapproved Indication	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824089	DIRECT	Y	DE			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Miralax			C				Not Reported
	Lorazepam			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dilaudid			C				Not Reported
	Guiafenesin			C				Not Reported
	Aspirin			C				Not Reported
	Acetaminophen			C				Not Reported
	Mylanta Suspension			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824090	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clinical Trial Participant; Ischaemic Stroke; Product Use In Unapproved Indication; Vertebral Artery Occlusion	Remdesivir	Y	S	Intravenous drip	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824149	DIRECT	Y	RI			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824205	DIRECT	Y				67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Procedural Hypotension	Remdesivir			S				Gilead
	Azithromycin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Bumetanide			C				Not Reported
	Ceftriaxone			C				Not Reported
	D5/Ns			C				Not Reported
	Fentanyl			C				Not Reported
	Gemfibrozil			C				Not Reported
	Heparin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Sodium Phosphate			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824219	DIRECT	Y	HO, OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Dyspnoea	Remdesivir	Y		S	Intravenous bolus	Other Frequency:One Time;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824509	DIRECT	Y	HO, OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pneumonia; Sepsis	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824895	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Albumin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Bumetanide			C				Not Reported
	Chlorothiazide			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Lidocaine Patch			C				Not Reported
	Metronidazole			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
	Vecuronium			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824899	DIRECT	Y	HO			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Therapy Cessation	Remdesivir Eua	Y		S	Intravenous bolus			Gilead
	Chlorhexidine 0.12% Solution			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Ipratropium-Albuterol			C				Not Reported
	Multivitamin			C				Not Reported
	Rocuronium			C				Not Reported
	Sennosides-Docusate			C				Not Reported
	Hydromorphone			C				Not Reported
	Lorazepam			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824926	DIRECT	Y	OT			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Inflammatory Marker Increased; Therapy Cessation	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen Tab			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine Iv			C				Not Reported
	Metoprolol Iv			C				Not Reported
	Potassium & Sodium Phosphates Packet			C				Not Reported
	Potassium Chloride Tab			C				Not Reported
	Vancomycin Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824932	DIRECT	Y	OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Diphenhydramine			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Etomidate			C				Not Reported
	Fentanyl			C				Not Reported
	Levothyroxine			C				Not Reported
	Norepinephrine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Propofol			C				Not Reported
	Succinylcholine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824939	DIRECT	Y	DE			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824944	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Dyspnoea; Emphysema; Interstitial Lung Disease; Respiratory Failure; Tachycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported
	Albuterol			C				Not Reported
	Brovana			C				Not Reported
	Anoro Ellipta			C				Not Reported
	Lasix			C				Not Reported
	Prednisone			C				Not Reported

		Insulin			C						Not Reported
		Protonix			C						Not Reported
		Atorvastatin			C						Not Reported
		Metformin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824950	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Voriconazole Iv			C				Not Reported
	Enoxaparin			C				Not Reported
	Fluconazole			C				Not Reported
	Fluticasone Nasal Spray			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levothyroxine			C				Not Reported
	Senna			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Sodium Chloride 0.9% W/ 20 Meq Kcl			C				Not Reported
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Iopamidol			C				Not Reported
	Ondansetron			C				Not Reported
	Promethazine W/ Codeine			C				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824956	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Dose Calculation Error; Glomerular Filtration Rate	Remdesivir			S	Intravenous drip			Gilead
	Ascorbic Acid Po			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported

Decreased; Incorrect Dose Administered By Product; Sepsis	Cholecalciferol			C						Not Reported
	Cimetidine Po			C						Not Reported
	Furosemide Ivp And Gtt			C						Not Reported
	Zinc Gluconate Po			C						Not Reported
	Cisatricurium			C						Not Reported
	Epoprostenol Inhaled			C						Not Reported
	Fentanyl Infusion Vent Sedation			C						Not Reported
	Propofol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824960	DIRECT	Y	HO			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824966	DIRECT	Y	LT, OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea Increased; Dialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Tocilizumab			C				Not Reported
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported
	Fentanyl Continuous Infusion			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Albumin 25 Gm Infusion			C				Not Reported
	Famotidine 20 Mg Po			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Furosemide 40 Mg Iv			C				Not Reported
	Enoxaparin 40 Mg Sq			C				Not Reported
	Insulin Infusion			C				Not Reported
	Cisatracurium Infusion			C				Not Reported
	Meropenem			C				Not Reported
	Simvastatin 20 Mg			C				Not Reported

		Vitamin D 2000 Units			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824970	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Daily After 200mg;		Gilead
	Ascorbic Acid Po 1000mg Bid			C				Not Reported
	Atorvastatin 10mg Po Daily			C				Not Reported
	Ceftriaxone 1gm Iiv Daily			C				Not Reported
	Clopidogrel 75mg Po Daily			C				Not Reported
	Enoxaparin 90mg Sq Q12hrs			C				Not Reported
	Famotidine 20mg Iv Daily			C				Not Reported
	Insulin Lispro Sq Sliding Scale			C				Not Reported
	Loratadine 10mg Po Daily			C				Not Reported
	Methylprednisolone 125mg Iv Q12hrs			C				Not Reported
	Zinc 220mg Oral Bid			C				Not Reported
	Norco 5/325mg Po Q6hrs Prn			C				Not Reported
	Fentanyl Variable Rate Continuous Iv			C				Not Reported
	Norepinephrine Variable Rate Continuous Iv			C				Not Reported
	Propofol Variable Rate Continuous Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824973	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chromaturia; Fatigue; Therapy Cessation	Remdesivir	Y		S				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824977	DIRECT	Y				55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Rash Maculo-Papular	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Stribild			C				Not Reported
	Prezista			C				Not Reported
	Lovenox			C				Not Reported
	Solumedrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824979	DIRECT	Y	DE			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 250mg Iv			C				Not Reported
	Potassium Chloride Er 40meq Oral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824984	DIRECT	Y	OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir			S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported
	Acetaminophen 325 Mg			C				Not Reported
	Aspirin 81mg Ec			C				Not Reported
	Enoxaparin 40mg Sc Bid			C				Not Reported
	Pantoprazole 40mg Po Qday			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824989	DIRECT	Y	DE			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arrhythmia; Creatinine Renal Clearance Decreased; Encephalopathy; Respiratory Failure; Sudden Cardiac Death	Remdesivir Solution	S	Gilead
	Modafinil	C	Not Reported
	Trazodone	C	Not Reported
	Quetiapine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824990	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824991	DIRECT	Y	OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Bisacodyl			C				Not Reported
	Lansoprazole			C				Not Reported
	Metoclopramide			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Sennosides-Docusate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824992	DIRECT	Y	HO			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir Injection			S	Intravenous drip			Gilead
	Remdesivir For Injection, Lyophilized Powder, 100 Mg Vial			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824993	DIRECT	Y				79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Administration Site Extravasation	Remdesivir			S	Intravenous drip		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825230	EXPEDITED (15-DAY)		DE, OT	US-SA-2020SA135575			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Heparin			C	Unknown	Unk		Not Reported
	Fenofibrate			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported
	Sodium Chloride			C	Unknown	Unk		Not Reported
	Sitagliptin			C	Unknown	Unk		Not Reported
	Midazolam			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Nph Insulin			C	Unknown	Unk		Not Reported
	Insulin Human;Insulin Human Injection, Isophane			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826568	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0467857		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not	100 Mg, Qd		Gilead

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826584	EXPEDITED (15-DAY)			US-GILEAD-2020-0467774			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17827902	DIRECT	Y	DS, HO, LT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crystal Nephropathy; Hydronephrosis; Renal Tubular Necrosis; Respiratory Disorder; Urine Analysis Abnormal	Remdesivir			S	Intravenous drip			Gilead
	Acetominophen			C				Not Reported
	Duonebs			C				Not Reported
	Amiodarone 150mg Iv Bolus Once			C				Not Reported
	Azithromycin 500mg Iv Once			C				Not Reported
	Cefepime 2gm Iv			C				Not Reported
	Potassium Chloride 20meq Iv			C				Not Reported
	Tocilizumab 400mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17827908	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Condition Aggravated; Enteritis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin			C				Not Reported
	Lovenox			C				Not Reported
	Imodium			C				Not Reported
	Losartan			C				Not Reported
	Pantoprazole			C				Not Reported
	Phosphorus			C				Not Reported
	Toradol			C				Not Reported

	Lopressor				C					Not Reported
	Metoprolol				C					Not Reported
	Aspirin				C					Not Reported
	Diltiazem				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17827943	DIRECT	Y	DE			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia; Cardio-Respiratory Arrest; Hypotension; Respiratory Failure	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17827959	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17828102	DIRECT	Y				85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gallbladder Disorder; Hepatic Enzyme Increased	Remdesivir 100 Mg/20 Ml			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17828289	DIRECT	Y				81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased	Remdesivir (Eua) 100 Mg Vial			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			Gilead
	Remicade Inj 100mg Vial			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Acetazolamide			C				Not Reported
	Azithromycin			C				Not Reported
	Cellralxone			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Nph			C				Not Reported
	Lansoprazole			C				Not Reported
	Linozolid			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828748	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17828807	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir	Y		S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829752	DIRECT	Y	OT			49 YR	Prefer not to disclose	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Injection	Y		S	Intravenous drip		3 DAY	Gilead
	Acetaminophen 500 Mg			C				Not Reported
	Albuterol 90 Mcg Hfa			C				Not Reported
	Ascorbic Acid 500 Mg			C				Not Reported
	Benzonatate 100 Mg			C				Not Reported
	Dexamethasone 20 Mg			C				Not Reported
	Dextromethorphan-Guaifenesin Cr 30-600			C				Not Reported
	Docusate 100 Mg			C				Not Reported
	Docusate-Senna 50/8.6 Mg			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Famotidine 20 Mg			C				Not Reported
	Guaifenesin 100/5			C				Not Reported
	Loperamide 2mg/15ml			C				Not Reported
	Ondansetron 4mg/2ml			C				Not Reported
	Zinc Sulfate 220mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829758	DIRECT	Y	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Ischaemic Hepatitis; Multi-Organ Disorder; Therapy Interrupted	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829764	DIRECT	Y				46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine	Remdesivir Injection			S	Intravenous (not	Other Frequency:Once;		Gilead

Phosphokinase Increased; Therapy Cessation			otherwise specified)			
	Remdesivir	S	Intravenous (not otherwise specified)	6 DAY	Gilead	
	Atorvastatin 40 Mg Tablet	C			Not Reported	
	Ceftriaxone 1 Gm Injection	C			Not Reported	
	Enoxaparin 100 Mg Injection	C			Not Reported	
	Furosemide 40 Mg Injection	C			Not Reported	
	Hydromorphone 1 Mg Injection	C			Not Reported	
	Hydroxychloroquine 200 Mg Tablet	C			Not Reported	
	Lorazepam 2 Mg Injection	C			Not Reported	
	Meropenem 1 Gm Injection	C			Not Reported	
	Pantoprazole 40 Mg Injection	C			Not Reported	
	Potassium Chloride Injection	C			Not Reported	
	Topiramate 100 Mg Tablet	C			Not Reported	
	Vancomycin 1 Gm Injection	C			Not Reported	
	Propofol 10 Mg/Ml Injection	C			Not Reported	
	Sodium Bicarbonate Injection	C			Not Reported	
	Vecuronium Injection	C			Not Reported	
	Acetaminophen Tablet	C			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830125	EXPEDITED (15-DAY)			US-GILEAD-2020-0468001		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue	Remdesivir			S	Unknown	200 Mg		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17830843	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20200514694		61 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous	Haldol			S	Unknown			Janssen
	Ceftriaxone			S	Unknown			Not Reported
	Clarithromycine			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported

Remdesivir	S	Unknown	Not Reported
Amlodipine	S	Unknown	Not Reported
Anxiolit	S	Unknown	Not Reported
Clexane	S	Unknown	Not Reported
Clexane	S	Unknown	Not Reported
Dafalgan	S	Unknown	Not Reported
Dafalgan	S	Unknown	Not Reported
Lasix /00032601/	S	Unknown	Not Reported
Lasix /00032601/	S	Unknown	Not Reported
Lasix /00032601/	S		Not Reported
Nexium /01479302/	S	Unknown	Not Reported
Nexium /01479302/	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Temesta /00273201/	S	Unknown	Not Reported
Diamox /00016901/	C		Not Reported
Diamox /00016901/	C		Not Reported
Diamox /00016901/	C		Not Reported
Distraneurin /00027501/	C		Not Reported
Novorapid	C		Not Reported
Ipramol	C		Not Reported
Heparine /00027701/	C		Not Reported
Lexotanil	C		Not Reported
Movicol	C		Not Reported
Morphine	C		Not Reported
Nozinan /00038601/	C		Not Reported
Solu-Medrol	C		Not Reported
Dexdor	C		Not Reported
Dexdor	C		Not Reported
Dexdor	C		Not Reported
Sintenyl	C		Not Reported
Sintenyl	C		Not Reported
Dormicum /00036201/	C		Not Reported
Dormicum /00036201/	C		Not Reported
Dormicum /00036201/	C		Not Reported
Noradrenaline /00127501/	C		Not Reported
Noradrenaline /00127501/	C		Not Reported

		Noradrenaline /00127501/			C					Not Reported
		Propofol			C					Not Reported
		Propofol			C					Not Reported
		Propofol			C					Not Reported
		Propofol			C					Not Reported
		Rocuronium			C					Not Reported
		Tracrium			C					Not Reported
		Tracrium			C					Not Reported
		Tracrium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17831674	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468136		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Digoxin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Methylprednisolon [Methylprednisolone]			C		Unk		Not Reported
	Nebivolol			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833395	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833398	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833410	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir Injection	Y		S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Heparin			C				Not Reported
	Hydralazine			C				Not Reported
	Loperamide			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sodium Chloride			C				Not Reported
	Multivitamin			C				Not Reported
	Ondansetron			C				Not Reported
	Dextromethorphan-Guaifenesin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Docusate-Senna			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833414	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Acute Respiratory Failure;	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Amiodarone Infusion			C				Not Reported

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Hypoxia; Shock; Viral Cardiomyopathy	Ceftriaxone			C					Not Reported
	Dobutamine Infusion			C					Not Reported
	Doxycycline Iv			C					Not Reported
	Enoxaparin 40mg Q12			C					Not Reported
	Famotidine 20mg Iv Q12			C					Not Reported
	Fentanyl Infusion			C					Not Reported
	Hydrocortisone 50mg Iv Q6hr			C					Not Reported
	Midazolam Infusion			C					Not Reported
	Norepinephrine Infusion			C					Not Reported
	Phenylephrine Infusion			C					Not Reported
	Propofol Infusion			C					Not Reported
	Sodium Bicarbonate Inusion			C					Not Reported
	Vasopressin Infusion			C					Not Reported
	Digoxin Bolus Iv			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833420	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833421	DIRECT	Y	OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epigastric Discomfort; Nausea	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Iohexol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833426	DIRECT	Y	DE			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Cardiac Arrest; Lethargy; Pneumothorax; Respiratory Failure	Remdesivir Solution			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Aztreonam			C				Not Reported
	Bisacodyl			C				Not Reported
	Buspirone			C				Not Reported
	Carbidopa-Levodopa			C				Not Reported
	Celebrex			C				Not Reported
	Clonazepam			C				Not Reported
	Digoxin			C				Not Reported
	Depakote			C				Not Reported
	Lovenox			C				Not Reported
	Fentanyl			C				Not Reported
	Guaifenesin Er			C				Not Reported
	Metoprolol			C				Not Reported
	Propofol			C				Not Reported
	Risperidone			C				Not Reported
	Dexmedetomindine Additive			C				Not Reported
	Epinephrine			C				Not Reported
	Fentalnyl			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833433	DIRECT	Y	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Injection	Y		S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported

		Budesonide-Formoterol			C					Not Reported
		Ceftriaxone			C					Not Reported
		Cholecalciferol			C					Not Reported
		Dexamethasone			C					Not Reported
		Docusate-Senna			C					Not Reported
		Enoxaparin			C					Not Reported
		Insulin Lispro			C					Not Reported
		Insulin Glargine			C					Not Reported
		Linagliptin			C					Not Reported
		Lisinopril			C					Not Reported
		Pantoprazole			C					Not Reported
		Polyethylene Glycol			C					Not Reported
		Selinexor			C					Not Reported
		Tramadol			C					Not Reported
		Zinc Sulfate			C					Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
27-May-2020	17833438	DIRECT	Y					43 YR	Male	USA
Preferred Term		**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**		**Mfr**
Hypokalaemia		Remdesivir			S	Intravenous bolus		10 DAY		Gilead
		Cefepime			C					Not Reported
		Enoxaparin			C					Not Reported
		Acetylcysteine Inh. Solution 20%			C					Not Reported
		Albuterol-Ipratropium Inh. Solution			C					Not Reported
		Amlodipine			C					Not Reported
		Enteral Nutrition (Vital Hp)			C					Not Reported
		Famotidine			C					Not Reported
		Piperacillin/Tazobactam			C					Not Reported
		Vancomycin			C					Not Reported
		Fentanyl			C					Not Reported
		Insulin Lispro			C					Not Reported
		Propofol			C					Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
27-May-2020	17833450	DIRECT	Y					52 YR	Female	USA
Preferred Term		**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**		**Mfr**

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833453	DIRECT	Y	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir	Y		S	Intravenous bolus		1 DAY	Gilead
	Acetaminophen Prn			C				Not Reported
	Albuterol Hfa Mdi			C				Not Reported
	Ascorbic Acid (Vitamin C) 1000mg Po Tid			C				Not Reported
	Bisacodyl Supp Daily Prn			C				Not Reported
	Enoxaparin 40mg Subq Q12hr			C				Not Reported
	Guaifenesin/Codeine Prn Cough			C				Not Reported
	Tussionex Po Bid			C				Not Reported
	Solu-Medrol 40mg Iv Q12hr			C				Not Reported
	Morphine Iv Prn			C				Not Reported
	Sodium Chloride Iv Solution			C				Not Reported
	Thiamine 100mg Tablet Po Daily			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported
	Chlorhexidine Swish/Spit Bid			C				Not Reported
	Famotidine 20mg Po Bid			C				Not Reported
	Mupirocin 2% Ointment Nasal Bid			C				Not Reported
	Thiamine 100mg Iv Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833459	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Glomerular Filtration Rate Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833468	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Remdesivir			S				Not Reported
	Atorvastatin			C				Not Reported
	Bumetanide			C				Not Reported
	Carvedilol			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Detemir			C				Not Reported
	Melatonin			C				Not Reported
	Meropenem			C				Not Reported
	Warfarin			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833473	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported
	Aztreonam			C				Not Reported
	Levaquin			C				Not Reported
	Pravastatin			C				Not Reported
	Sirolimus			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833477	DIRECT		OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Remdesivir			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833483	DIRECT	Y	DE			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Arrest	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Covid-19 Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833489	DIRECT	Y	DE			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Diarrhoea; Malaise; Pyrexia	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Apixaban			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine Oral Solution			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin (Lispro, Regular)			C				Not Reported
	Lactated Ringers			C				Not Reported
	Latanoprost Drops			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Metronidazole			C				Not Reported
	Modafinil			C				Not Reported
	Mometasone/Formoterol			C				Not Reported
	Montelukast			C				Not Reported
	Morphine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sertraline			C				Not Reported
	Sodium Chloride 0.9% Infusion			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833490	DIRECT	Y	DE			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Respiratory Failure; Cough; Dyspnoea; Hypoxia; Renal Impairment; Sepsis	Remdesivir			S	Intravenous bolus			Gilead
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine Oral Solution			C				Not Reported
	Normosol-R			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone Iv			C				Not Reported
	Triad Paste Wound Dressing			C				Not Reported
	Insulin (Glargine, Regular)			C				Not Reported
	Lactated Ringers			C				Not Reported
	Lactulose			C				Not Reported
	Magnesium Sulfate Iv			C				Not Reported
	Melatonin			C				Not Reported
	Metronidazole			C				Not Reported
	Midazolam			C				Not Reported
	Midodrine			C				Not Reported
	Morphine Sulfate			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833492	DIRECT		OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833505	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; General Physical Health Deterioration; Haemoglobin Decreased; Intestinal Dilatation; Intestinal Ischaemia; Lactic Acidosis; Neutrophil Count Decreased; Platelet Count Decreased; Septic Shock; Supraventricular Tachycardia; Tissue Infiltration	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Amiodarone			C				Not Reported
	Albumin			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Folic Acid			C				Not Reported
	Heparin Sq			C				Not Reported
	Enoxaparin Sq			C				Not Reported
	Famotidine			C				Not Reported
	Hydrocortisone Sodium Succinate			C				Not Reported
	Midodrine			C				Not Reported
	Multivitamin			C				Not Reported
	Nicotine Transdermal			C				Not Reported
	Thiamine			C				Not Reported
	Dobutamine Infusion			C				Not Reported
	Epineprhrine Infusion			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Ketamine Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Phenylephrine Infusion			C				Not Reported
	Vasopressin Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833510	DIRECT	Y	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Albumin			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Cefepime			C				Not Reported

			Enoxaparin			C				Not Reported
			Furosemide			C				Not Reported
			Insulin Glargine			C				Not Reported
			Insulin Lispro			C				Not Reported
			Levofloxacin			C				Not Reported
			Methylprednisolone			C				Not Reported
			Pantoprazole			C				Not Reported
			Sertraline			C				Not Reported
			Vancomycin			C				Not Reported
			Fentanyl			C				Not Reported
			Midazolam			C				Not Reported
			Norepinephrine			C				Not Reported
			Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833527	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Rhabdomyolysis	Remdesivir			S	Intravenous (not otherwise specified)		4 DAY	Not Reported
	Sinemet			C				Not Reported
	Fentanyl			C				Not Reported
	Reglan			C				Not Reported
	Midodrine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Pepcid			C				Not Reported
	Lovenox			C				Not Reported
	Solumedrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833532	DIRECT	Y	OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833533	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Not Reported
	Zithromax			C				Not Reported
	Rocephin			C				Not Reported
	Lovenox			C				Not Reported
	Solumedrol			C				Not Reported
	Humalog			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833539	DIRECT	Y	HO			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Headache; Heart Rate Increased; Migraine; Myalgia; Pain; Pruritus; Rash Papular	Remdesivir Injection	Y		S	Iontophoresis	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833545	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833603	DIRECT	Y	HO, LT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bacterial Infection; White Blood Cell Count Increased	Remdesivir			S						Not Reported
	Aspirin 81mg			C						Not Reported
	Atorvastatin 10mg			C						Not Reported
	Famotidine 20mg			C						Not Reported
	Furosemide 20mg			C						Not Reported
	Lorazepam 2mg			C						Not Reported
	Sodium Chloride			C						Not Reported
	Vancomycin			C						Not Reported
	Heparin			C						Not Reported
	Insulin Aspart			C						Not Reported
	Insulin Detemir			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833610	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pyrexia; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin Ec			C				Not Reported
	Atorvastatin			C				Not Reported
	Benztropine			C				Not Reported
	Carvedilol			C				Not Reported
	Divalproex			C				Not Reported
	Donepezil			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Guaifenesin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Regular Human			C				Not Reported
	Ipratropium/Albuterol Inhalation			C				Not Reported
	Loratadine			C				Not Reported
	Methylprednisolone Sodium Succinate			C				Not Reported
	Montelukast			C				Not Reported
	Ibrutinib			C				Not Reported
	Pantoprazole			C				Not Reported
	Also: Quetiapine, Tamsulosin,			C				Not Reported

Zinc Sulfate, & Zosyn

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833630	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833637	DIRECT	Y	DE			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir For Eua	Y		S				Gilead
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833642	DIRECT	Y	LT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulseless Electrical Activity; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Enoxaparin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833647	DIRECT	Y				42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Tremor	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Enoxaparin			C				Not Reported
	Insulin Glargine (Lantus)			C				Not Reported
	Insulin Lispro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833652	DIRECT	Y	HO, OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; International Normalised Ratio Increased; Liver Disorder; Prothrombin Time Prolonged	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Unknown
	Actemra			C				Not Reported
	Plaquinil			C				Not Reported
	Ceftiraxone			C				Not Reported
	Doxycycline			C				Not Reported
	Vancomycin			C				Not Reported
	Vit C			C				Not Reported
	Torsemide			C				Not Reported
	Cardizem			C				Not Reported
	Lipitor			C				Not Reported
	Protonix			C				Not Reported
	Metoprolol Xl			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833668	DIRECT	Y				40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833677	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dyspnoea; Hypoxia; Lethargy; Respiratory Disorder	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833720	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833738	DIRECT	Y				1 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Product Formulation Administered; Product Dispensing Error; Product Use Issue; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833753	DIRECT		DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833766	DIRECT		OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17839011	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833859	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Lethargy; Oxygen Saturation Decreased; Palpitations; Tremor; Ventricular Tachycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once (Loading Dose;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834192	DIRECT	Y	OT			92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased;	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

Glomerular Filtration Rate Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834582	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Ipratropium			C				Not Reported
	Metoprolol			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin			C				Not Reported
	Diltiazem			C				Not Reported
	Fentanyl			C				Not Reported
	Morphine			C				Not Reported
	Allopurinal			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Lorazepam			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834588	DIRECT	Y	DE, OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Febrile Neutropenia; Respiratory Failure	Remdesivir			S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834593	DIRECT	Y	LT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir	Y	S	Intravenous bolus	Gilead
	Atorvastatin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834597	DIRECT	Y	DE			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Condition Aggravated; Hypotension; Inflammatory Marker Increased; Ventricular Fibrillation	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen 650mg Tablet			C				Not Reported
	Cefepime 2g Ivpb			C				Not Reported
	Dexmedetomidine 1.4mg/Kg/Hr Infusion			C				Not Reported
	Enoxaparin 40mg Bid			C				Not Reported
	Etomidate 20mg Once			C				Not Reported
	Fentanyl 100mcg Once			C				Not Reported
	Insulin Glargine 5 Units Bid			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Lorazepam 1mg Inj Once			C				Not Reported
	Insulin Regular Sliding Scale			C				Not Reported
	Midazolam 5mg Inj Once			C				Not Reported
	Propofol Infusion			C				Not Reported
	Rocuronium Infusion			C				Not Reported
	Vancomycin 1250mg Q6h			C				Not Reported
	Magnesium Oxide 400mg Bid			C				Not Reported
	Potassium Chloride 40meq Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834603	DIRECT	Y	DS			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Pressure Decreased; Blood Urea Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:1 Time & 100 Daily;		Gilead
	Lovenox 40mg			C				Not Reported
	Docusate With Senna			C				Not Reported
	Famotidine			C				Not Reported

		Lantus			C					Not Reported
		Insulin Lispro			C					Not Reported
		Lisinopril			C					Not Reported
		Acetaminophen			C					Not Reported
		Fentanyl Drip			C					Not Reported
		Lactated Ringers			C					Not Reported
		Norepinephrine			C					Not Reported
		Propofol			C					Not Reported
		Rocuronium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834607	DIRECT		DE			92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834613	DIRECT	Y	DE			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hypoxia	Remdesivir	Y		S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834623	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Insulin			C				Not Reported

	Linezolid	C	Not Reported
	Meropenem	C	Not Reported
	Lorazepam	C	Not Reported
	Phenylephrine	C	Not Reported
	Propofol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834646	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834651	DIRECT	Y	DE			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Clinical Trial Participant; Liver Function Test Increased; Multiple Organ Dysfunction Syndrome; Product Use In Unapproved Indication; Shock	Remdesivir			S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Norepinephrine Infusion			C				Not Reported
	Phenylephrine Infusion			C				Not Reported
	Vasopressin Infusion			C				Not Reported
	Epinephrine Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834885	DIRECT	Y	DE			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Product Use In Unapproved Indication; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834887	DIRECT	Y	DE			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palliative Care; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834892	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Dysphagia; Headache; Product Use In Unapproved Indication	Remdesivir			S				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834894	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S				Not Reported
	Amlodipine			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834895	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834911	DIRECT	Y				54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Valproic Acid			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834946	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Renal Tubular Necrosis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Morphine			C				Not Reported
	Duoneb			C				Not Reported
	Dextrose 50%			C				Not Reported
	Sodium Chloride Flush			C				Not Reported
	Sodium Chloride 250 Ml			C				Not Reported
	Potassium Chloride			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Bumetanide			C				Not Reported
	Methylprednisolone			C				Not Reported
	Insulin Lispro			C				Not Reported
	Chlorothiazide			C				Not Reported
	Vancomycin			C				Not Reported
	Insulin Detemir			C				Not Reported
	Tocilzumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834965	DIRECT	Y	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Interrupted	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834973	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834979	DIRECT	Y				84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Platelet Count Increased; White Blood Cell Count Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acyclovir 400 Mg Po Bid			C				Not Reported
	Allopurinol 300 Mg Po Daily			C				Not Reported
	Aspirin 325 Mg Po Daily			C				Not Reported
	Cholecalciferol 2000 Units Po Daily			C				Not Reported
	Furosemide 20 Mg Po Bid			C				Not Reported
	Levothyroxine 88 Mcg Po Daily			C				Not Reported
	Meropenem 1 Gram Iv Q12h			C				Not Reported
	Ruxolitinib			C				Not Reported
	Heparin Iv Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835864	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468283		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Aspartate Aminotransferase Increased; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Ceftriaxone			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17837791	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-GILEAD-2020-0469042		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hydronephrosis; Necrosis; Renal Impairment; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Duoneb			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838503	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Renal Impairment	Remdesivir			S	Intravenous drip			Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Midazolam			C				Not Reported
	Rocuronium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838778	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin Tablet			C				Not Reported
	Ceftriaxone Injection			C				Not Reported
	Enoxaparin Injection			C				Not Reported
	Furosemide Injection			C				Not Reported
	Guaifenesin Tablet			C				Not Reported
	Hydroxychloroquine Tablet			C				Not Reported
	Lansoprazole Capsule			C				Not Reported
	Levothyroxine Tablet			C				Not Reported
	Methylprednisolone Injection			C				Not Reported
	Pantoprazole Tablet			C				Not Reported
	Vancomycin Injection			C				Not Reported
	Propofol Injection			C				Not Reported
	Acetaminophen Tablet			C				Not Reported
	Alprazolam Tablet			C				Not Reported
	Lorazepam Injection			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838938	DIRECT	Y				33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Remdesivir	Y		S	Intravenous drip			Gilead

Aminotransferase Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838945	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838949	DIRECT	Y				90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838954	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir	Y		S	Intravenous drip			Gilead
	Fenatnyl			C				Not Reported
	Nimbex			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Cetriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838955	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Ischaemic Hepatitis; Transaminases Increased	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Azithromycin	C				Not Reported
	Ceftriaxone	C				Not Reported
	Dexamethasone	C				Not Reported
	Enoxaparin	C				Not Reported
	Famotidine	C				Not Reported
	Fentanyl	C				Not Reported
	Insulin Glargine	C				Not Reported
	Insulin Lispro	C				Not Reported
	Phenylephrine	C				Not Reported
	Piperacillin/Tazobactam	C				Not Reported
	Propofol	C				Not Reported
	Rocuronium	C				Not Reported
	Zinc Sulfate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838959	DIRECT	Y	HO, LT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838962	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Oral			Gilead
	Cefepime			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Aripiprazole			C				Not Reported
	Gabapentin			C				Not Reported
	Mirtazapine			C				Not Reported
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Aspirin			C				Not Reported

		Famotidine			C					Not Reported
		Prazosin			C					Not Reported
		Tamsulosin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838968	DIRECT	Y				82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Eliquis 2.5mg Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838972	DIRECT	Y	LT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838976	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hypotension; Infusion Site Extravasation; Infusion Site Reaction; Nausea	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838982	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration Rate	Remdesivir			S	Intravenous drip			Gilead

Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838987	DIRECT	Y				91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838988	DIRECT	Y	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838991	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838994	DIRECT	Y				77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Blood Creatine Increased; Creatinine Renal Clearance Decreased; Glomerular Filtration Rate Decreased	Remdesivir	S	Intravenous drip	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838997	DIRECT	Y				32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17839001	DIRECT	Y	LT, OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous drip			Gilead
	Rocuronium			C				Not Reported
	Sodium Bicarbonate 50 Meq			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Drip			C				Not Reported
	Morphine			C				Not Reported
	Propofol			C				Not Reported
	Zosyn			C				Not Reported
	Azithromycin			C				Not Reported
	Bumex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17839004	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported

	Allopurinol	C	Not Reported
	Amiodarone	C	Not Reported
	Aspirin	C	Not Reported
	Atorvastatin	C	Not Reported
	Cardidopa-Levodapa	C	Not Reported
	Diltiazem	C	Not Reported
	Enoxaparin	C	Not Reported
	Furosemide	C	Not Reported
	Hydrocodone-Acetaminophen	C	Not Reported
	Insulin Aspart	C	Not Reported
	Insulin Glargine	C	Not Reported
	Methylprednisolone	C	Not Reported
	Metoprolol Tartrate	C	Not Reported
	Sertraline	C	Not Reported
	Topiramate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17839023	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Fibrillation	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17839025	DIRECT	Y				54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17839026	DIRECT	Y	DE			88 YR	Female	AFG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Hypoxia; Skin Discolouration	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Aztreonam			C				Not Reported

	Ceftriaxone			C						Not Reported
	Pumozyne			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17839552	DIRECT	Y	HO, RI, OT			94 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Remdesivir 100mg/20ml			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17839768	DIRECT	Y				32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839763	DIRECT	Y				76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Remdesivir Injection			S	Intravenous bolus	Other Frequency:200mg X1;		Gilead
	Amlodipine			C				Not Reported
	Enoxaparin			C				Not Reported
	Metoprolol Xl			C				Not Reported
	Prazosin			C				Not Reported
	Probenecid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839790	DIRECT	Y	DE			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dialysis; Renal Failure; Tachypnoea	Remdesivir	S	Intravenous bolus		Gilead
	Acetaminophen	C			Not Reported
	Amlodipine	C			Not Reported
	Aspirin	C			Not Reported
	Atorvastatin	C			Not Reported
	Benzonatate	C			Not Reported
	Normosol-R	C			Not Reported
	Enoxaparin	C			Not Reported
	Fentanyl	C			Not Reported
	Furosemide	C			Not Reported
	Guaifenesin/Codeine	C			Not Reported
	Heparin	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Hydromorphone	C			Not Reported
	Insulin (Glargine, Lispro And Regular)	C			Not Reported
	Labetolol	C			Not Reported
	Lactated Ringers	C			Not Reported
	Levothyroxine	C			Not Reported
	Lidocaine/Epinephrine	C			Not Reported
	Lorazepam	C			Not Reported
	Magnesium Sulfate	C			Not Reported
	Morphine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839798	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis; Pneumothorax; Pseudomonal Bacteraemia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalecent Plasma			C				Not Reported
	Tocilizumab Or Matching Placebo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839805	DIRECT	Y	DE			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fluid Overload; Hypotension	Remdesivir Solution			S	Intravenous (not otherwise specified)					Gilead
	Convalescent Plasma			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839841	DIRECT	Y	OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Flushing; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once Then 100mg X4;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839991	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840013	DIRECT	Y	DE			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840020	DIRECT	Y	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir			S				Not Reported

Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Hyperhidrosis; Liver Function Test Increased; Therapy Cessation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840027	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Dialysis; Disease Progression	Remdesivir	Y		S				Gilead
	Aspirin			C				Not Reported
	Atovastatin			C				Not Reported
	Calcium Citrate/Vitamin D			C				Not Reported
	Cefazolin			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Hydrocortisone			C				Not Reported
	Lansoprazole			C				Not Reported
	Naloxegol			C				Not Reported
	Multivitamin			C				Not Reported
	Tacrolimus			C				Not Reported
	Tenofovir			C				Not Reported
	Atracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840033	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Continuous	Remdesivir			S	Intravenous (not			Gilead

Haemodiafiltration; Creatinine Renal Clearance Decreased; Endotracheal Intubation; Renal Impairment; Therapy Cessation

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840034	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Cardio-Respiratory Arrest; Pulse Absent; Shock	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840052	DIRECT	Y	OT			55 YR	Male	XQZ

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Remdesivir			S	Intravenous drip			Not Reported
	Rocuronium			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Hydromorphone			C				Not Reported
	Fluoxetine			C				Not Reported
	Fentanyl			C				Not Reported
	Ceftriaxone			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840058	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine	Remdesivir			S	Intravenous bolus			Gilead

Increased; C-Reactive Protein Increased; Fibrin D Dimer Increased; Glomerular Filtration Rate Decreased; Haematuria; Interleukin Level Increased; Seizure	Acetylcysteine 20% Oral Solution	C		Not Reported
	Aztreonam	C		Not Reported
	Furosemide	C		Not Reported
	Levofloxacin	C		Not Reported
	Tocilizumab	C		Not Reported
	Acetaminophen	C		Not Reported
	Albuterol	C		Not Reported
	Atropine 1% (Orally)	C		Not Reported
	Clopidogrel	C		Not Reported
	Docusate	C		Not Reported
	Heparin Subq	C		Not Reported
	Levothyroxine	C		Not Reported
	Midazolam	C		Not Reported
	Norepinephrine	C		Not Reported
	Pantoprazole	C		Not Reported
	Propofol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840084	DIRECT	Y				79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Remdesivir	Y		S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840087	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Hypoxia; Respiratory Failure; Severe Acute Respiratory Syndrome	Remdesivir 100mg/20 Ml			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Carbidopa-Levodopa			C				Not Reported
	Donepezil			C				Not Reported
	Enoxaprin			C				Not Reported

		Etomidate			C						Not Reported
		Lispro			C						Not Reported
		Insulin			C						Not Reported
		Metoprolol			C						Not Reported
		Montelukast			C						Not Reported
		Solifenecin			C						Not Reported
		Acetaminophen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840213	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Distributive Shock; Drug Ineffective	Remdesivir 100mg/20 Ml Eua			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	 Frequency 4x		Gilead
	Colace			C				Not Reported
	Eliquis			C				Not Reported
	Humalog			C				Not Reported
	Insulin			C				Not Reported
	Lantus			C				Not Reported
	Pepcid			C				Not Reported
	Miralax			C				Not Reported
	Seroquel			C				Not Reported
	Singulair			C				Not Reported
	Zofran			C				Not Reported
	Acetaminophen			C				Not Reported
	Piperacillin Tazobactam			C				Not Reported
	Azithromycin			C				Not Reported
	Diclofenac			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Exmedetomidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840266	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Blood Bilirubin Increased; Blood Creatinine Increased; Dehydration; Hypotension; Transaminases Increased	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead
	Fentanyl Drip		C		Not Reported
	Norepinephrine Drip		C		Not Reported
	Rocuronium Drip		C		Not Reported
	Furosemide Ivp X1		C		Not Reported
	Gabapentin		C		Not Reported
	Lovenox		C		Not Reported
	Famotidine		C		Not Reported
	Lactated Ringers		C		Not Reported
	Acetaminophen		C		Not Reported
	Ketamine		C		Not Reported
	Propofol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17840269	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Furosemide Iv			C				Not Reported
	Furosemide Po			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841424	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468719		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Norepinephrine			C		2-10 Mcg/Min		Not Reported
	Acetaminophen			C				Not Reported
	Albumin			C				Not Reported
	Azithromycin			C				Not Reported
	Bumetanide			C				Not Reported

	Ceftriaxone	C			Not Reported
	Clonazepam	C			Not Reported
	Desmopressin	C			Not Reported
	Docusate	C			Not Reported
	Enoxaparin	C			Not Reported
	Epoprostenol	C			Not Reported
	Famotidine	C			Not Reported
	Fentanyl	C			Not Reported
	Furosemide	C			Not Reported
	Heparin	C			Not Reported
	Hydromorphone	C			Not Reported
	Ketamine	C			Not Reported
	Insulin	C			Not Reported
	Midodrine	C			Not Reported
	Phenylephrine	C		25-50 Mcg/Min	Not Reported
	Propofol	C			Not Reported
	Rocuronium	C			Not Reported
	Sennosides	C			Not Reported
	Dopamine	C		1-7 Mcg/Kg/Min	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842483	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468473		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydromorphone			C				Not Reported
	Acetaminophen			C				Not Reported
	Zofran [Ondansetron]			C				Not Reported
	Vitamin D3			C				Not Reported
	Titralac [Calcium Carbonate]			C				Not Reported
	Seroquel			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Miralax			C				Not Reported
	Benadryl [Diphenhydramine			C				Not Reported

	Hydrochloride]		
	Levophed	C	Not Reported
	Magnesium Sulfate	C	Not Reported
	Potassium Chloride	C	Not Reported
	Clozaril	C	Not Reported
	Propofol	C	Not Reported
	Amidate [Etomidate]	C	Not Reported
	Quelicin	C	Not Reported
	Fentanyl	C	Not Reported
	Versed	C	Not Reported
	Humuline Regular	C	Not Reported
	Humalog	C	Not Reported
	Ancef [Cefazolin Sodium]	C	Not Reported
	Protonix [Omeprazole]	C	Not Reported
	Flagyl [Metronidazole]	C	Not Reported
	Rocephin [Ceftriaxone]	C	Not Reported
	Vancomycin	C	Not Reported
	Zenpep	C	Not Reported
	Prilosec [Omeprazole]	C	Not Reported
	Potassium Bicarbonate	C	Not Reported
	Zemuron	C	Not Reported
	Levaquin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842537	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468948		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17844971	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Not Reported
	Prenisone`			C				Not Reported
	Augmentin			C				Not Reported
	Sertraline			C				Not Reported
	Apixiban			C				Not Reported

			Apriso			C				Not Reported
			Divalproex			C				Not Reported
			Cetirizine			C				Not Reported
			Ferrous Gluconate			C				Not Reported
			Guaifenesin			C				Not Reported
			Hydroxyzine			C				Not Reported
			Loperamide			C				Not Reported
			Metoprolol Succinate Xl			C				Not Reported
			Omeprazole			C				Not Reported
			Polyethylene Glycol			C				Not Reported
			Spironolactone			C				Not Reported
			Tamsulosin			C				Not Reported
			Metoprol Tartrate			C				Not Reported
			Zosyn			C				Not Reported
			Saline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17844976	DIRECT	Y	HO			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Setraline			C				Not Reported
	Melatonin			C				Not Reported
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Ketorolac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17844978	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Heart Rate Irregular	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17844983	DIRECT	Y				47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Hyperhidrosis; Hypotension	Remdesivir	Y		S	Parenteral			Gilead
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17844998	DIRECT	Y	HO			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845001	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Creatinine Increased; International Normalised Ratio Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845002	DIRECT	Y	DS			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Quadriparesis	Remdesivir			S	Intravenous drip	Other Frequency:X1 Loading Dose;		Gilead
	Senna			C				Not Reported
	Melatonin			C				Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Doxycycline Iv			C				Not Reported
	Clindamycin Iv			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Glycolax			C				Not Reported
	Peridex			C				Not Reported
	Acetaminophen Po			C				Not Reported
	Precedex			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Acyclovir Iv			C				Not Reported
	Etomidate			C				Not Reported
	Omnipaque			C				Not Reported
	Lorazepam			C				Not Reported
	Midazolam			C				Not Reported
	Rocuronium			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845005	DIRECT	Y				23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845007	DIRECT	Y	OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous drip			Gilead
	Osmolite 1.5 Cal Liquid			C				Not Reported
	Atorvastatin 10mg At Bedtime			C				Not Reported
	Chlorhexidine Mouthwash			C				Not Reported
	Doxepin 10mg			C				Not Reported
	Ensure Clnical Health			C				Not Reported
	Erythromycin Opth Ointment			C				Not Reported

			Twice Daily							
			Furosemide 40mg Iv Once		C					Not Reported
			Heparin In D5w 25000 Unit Bag		C					Not Reported
			Propofol 1000mg Titration		C					Not Reported
			Sodium Chloride 0.9% @ 50ml/Hr		C					Not Reported
			Acetaminophen 325mg Tablet		C					Not Reported
			Lorazepam 1mg Injection Once		C					Not Reported
			Noepinephrine 4mg In 500ml Dextrose 5%		C					Not Reported
			Hydroxychloroquine 200mg		C					Not Reported
			Insulin Lispro Per Sliding Scale		C					Not Reported
			Levothyroxine 137mcg Per Dose		C					Not Reported
			Methylprednisolone 125mg Iv Every 6 Hrs		C					Not Reported
			Omega 3 Fatty Acid 2000mg Twice Daily		C					Not Reported
			Pantoprazole 40mg Iv Twice Daily		C					Not Reported
			Propranolol 40mg Twice Daily		C					Not Reported
			Sertraline 25mg Daily		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845012	DIRECT	Y	HO, OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Creatinine Increased; Therapy Interrupted; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cobicistat/ Elvitegravir/Emtracitabine			C				Not Reported
	Atorvastatin			C				Not Reported
	Doxycycline			C				Not Reported
	Omnipaque			C				Not Reported
	Ceftriaxone			C				Not Reported
	Norepinephrine			C				Not Reported
	Cisatricarium			C				Not Reported
	Cholecalciferol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Folic Acid			C				Not Reported
	Multivitamin			C				Not Reported

	Codeine-Guifenesin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845018	DIRECT	Y	LT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Therapy Interrupted	Remdesivir	Y		S				Gilead
	Azithromycin			C				Not Reported
	Duoneb			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Budesonide			C				Not Reported
	Chlorhexadine			C				Not Reported
	Enoxaparin			C				Not Reported
	Lasix			C				Not Reported
	Lantus			C				Not Reported
	Lactobacillus			C				Not Reported
	Methylprednisolone			C				Not Reported
	Oxycodone			C				Not Reported
	Pantoprazole			C				Not Reported
	Zosyn			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845059	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus	Other Frequency:X1;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Kaletra 400/100 Mg Bid Po			C				Not Reported
	Ivermectin 9mg Po Q48h X2 Doses			C				Not Reported
	Actemra 400mg X1			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845065	DIRECT	N	DE			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acidosis; Acute Kidney Injury; Blood Creatinine Increased; Blood Pressure Systolic Decreased; Bronchitis; Hypotension; Multiple Organ Dysfunction Syndrome; Oliguria; Pneumonia; Renal Impairment; Respiratory Failure; Sepsis	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Convalescent Plasma			C				Not Reported
	Azithromycin			C				Not Reported
	Medrol			C				Not Reported
	Amlodopine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Ceftriaxone			C				Not Reported
	Lovenox			C				Not Reported
	Insulin Lispro			C				Not Reported
	Zosyn			C				Not Reported
	Vacomycin			C				Not Reported
	Versed			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17845068	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Peripheral Swelling	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17846418	DIRECT	Y	RI, OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir 100mg/20ml			S	Intravenous (not otherwise specified)			Gilead

	Remdesivir 100mg/20ml	S	Intravenous (not otherwise specified)		Gilead
	Remdesivir 100mg/20ml	S	Intravenous (not otherwise specified)		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17846473	DIRECT	Y	RI, OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Atrial Fibrillation; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased; C-Reactive Protein Increased; Hypotension; Right Ventricular Systolic Pressure Increased; Serum Ferritin Increased	Remdesivir 100mg/20ml Vial			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845070	DIRECT	Y	DE, HO, LT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Emergency Use Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:X1 Loading Dose;		Gilead
	Emergency Use Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetominopohen			C				Not Reported
	Amlopidine			C				Not Reported
	Anastrozole			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported

			Cefepime			C				Not Reported
			Clopidogrel			C				Not Reported
			Combivent Respimat			C				Not Reported
			Compazine			C				Not Reported
			Cholecalciferol			C				Not Reported
			Clonidine			C				Not Reported
			Coreg			C				Not Reported
			Cyanocobalamin			C				Not Reported
			Docusate Senna			C				Not Reported
			Donepezil			C				Not Reported
			Enoxaparin			C				Not Reported
			Famotidine			C				Not Reported
			Ferrous Sulfate			C				Not Reported
			Folic Acid			C				Not Reported
			Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845071	DIRECT	Y	HO			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cerebrovascular Accident; Mental Status Changes	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency: Loading/Once Daily;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency: Loading/Once Daily;		Gilead
	Venlafaxine			C				Not Reported
	Topamax			C				Not Reported
	Namenda			C				Not Reported
	Imdur			C				Not Reported
	Neurontin			C				Not Reported
	Breo Ellipta			C				Not Reported
	Pepcid			C				Not Reported
	Aspirin			C				Not Reported
	Cardizem			C				Not Reported
	Levetiracetam			C				Not Reported
	Combivent			C				Not Reported
	Heparin			C				Not Reported
	Dextrose			C				Not Reported
	Morphine			C				Not Reported
	Rocephin			C				Not Reported

Zithromax	C		Not Reported
Nystatin	C		Not Reported
Cardizem	C		Not Reported
Tylenol	C		Not Reported
Eliquis	C		Not Reported
Sodium Chloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845076	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845081	DIRECT	Y	OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Laryngeal Oedema; Periorbital Swelling; Peripheral Swelling; Peripheral Swelling	Remdesivir	Y		S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845085	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845113	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Infusion Related Reaction; Nausea	Remdesivir			S	Intravenous (not otherwise specified)			7 DAY		Gilead
	Remdesivir			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845123	DIRECT	Y	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845128	DIRECT					48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Preparation Error; Product Preparation Error	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845130	DIRECT	Y	HO, OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17846348	DIRECT		HO				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Infusion Site Pain	Remdesivir (Eua)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17846639	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469017		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Famotidine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17845136	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Chronic Kidney Disease	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir (Eua)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17845140	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Thrombocytopenia	Remdesivir			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846453	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Lopinavir/Ritonavir			C				Not Reported
	Losartan			C				Not Reported

		Metformin Er			C					Not Reported
		Tocilizumab			C					Not Reported
		Aspirin			C					Not Reported
		Cefuroxime			C					Not Reported
		Famotidine			C					Not Reported
		Gabapentin			C					Not Reported
		Guaifenesin			C					Not Reported
		Hydrocholorthiazide			C					Not Reported
		Heparin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846476	DIRECT	Y				39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported
	Lovenox			C				Not Reported
	Ondansetron			C				Not Reported
	Tramadol			C				Not Reported
	Acetominophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846480	DIRECT	Y				51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission In Error	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846502	DIRECT	Y	HO			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

Increased; Therapy Cessation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846513	DIRECT		OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperphosphataemia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			C				Not Reported
	Docusate Sodium			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Detemir			C				Not Reported
	Insulin Humalog			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Metolazone			C				Not Reported
	Metoprolol			C				Not Reported
	Senna Liquid			C				Not Reported
	Bumetanide Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Heparin Infusion			C				Not Reported
	Insulin Human Regular			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846521	DIRECT		OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytosis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			C				Not Reported
	Docusate Sodium			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Detemir			C				Not Reported
	Insulin Humalog			C				Not Reported

		Magnesium Sulfate			C					Not Reported
		Metolazone			C					Not Reported
		Metoprolol			C					Not Reported
		Senna Liquid			C					Not Reported
		Bumetanide Drip			C					Not Reported
		Fentanyl Drip			C					Not Reported
		Heparin Infusion			C					Not Reported
		Insulin Human Regular			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846712	DIRECT	N	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir 5mg/Ml Concentrated Solution	Y		S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Other Dose:200mg/40ml; Frequency: 1 Dose Or Amount: 100/Mg/20ml Frequency: 2		Gilead
	Convalescent Plasma 213 Ml			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847828	EXPEDITED (15-DAY)			US-GILEAD-2020-0468846		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Storage Error	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848017	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0469288		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

	Tocilizumab			C					Not Reported
	Cefepime			C					Not Reported
	Azithromycin			C					Not Reported
	Fentanyl			C					Not Reported
	Midazolam			C					Not Reported
	Propofol			C					Not Reported
	Albumin			C					Not Reported
	Famotidine			C					Not Reported
	Aspirin 81			C					Not Reported
	Furosemide			C					Not Reported
	Enoxaparin			C					Not Reported
	Insulin			C					Not Reported
	Cisatracurium			C					Not Reported
	Meropenem			C					Not Reported
	Simvastatin			C					Not Reported
	Vitamin D [Colecalciferol]			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848022	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0469201		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endotracheal Intubation	Remdesivir			S	Unknown	Unk		Gilead
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Atorvastatin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Lorazepam			C				Not Reported
	Sodium Chloride			C				Not Reported
	Vancomycin			C				Not Reported
	Heparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Detemir			C				Not Reported
	Norepinephrine			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848028	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469174		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Renal Impairment	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Albuterol [Salbutamol]	C		Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Unk	Not Reported
	Cefepime	C		Unk	Not Reported
	Chlorhexidine	C		Unk	Not Reported
	Normosol R	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Heparin	C		Unk	Not Reported
	Hydrocortisone	C		Unk	Not Reported
	Triad	C		Unk	Not Reported
	Insulin Glargine	C		Unk	Not Reported
	Insulin Regular Hm	C		Unk	Not Reported
	Lactated Ringers	C		Unk	Not Reported
	Lactulose	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Melatonin	C		Unk	Not Reported
	Metronidazole	C		Unk	Not Reported
	Midazolam	C		Unk	Not Reported
	Midodrine	C		Unk	Not Reported
	Morphine Sulfate	C		Unk	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Phenylephrine	C		Unk	Not Reported
	Potassium Chloride	C			Not Reported
	Prismasate Bk0/3.5	C			Not Reported
	Prismasol Bgk	C			Not Reported
	Propofol	C			Not Reported

	Simvastatin			C						Not Reported
	Sodium Bicarbonate			C						Not Reported
	Vancomycin			C						Not Reported
	Zolpidem			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848039	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469173		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Apixaban			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Insulin Regular Hm			C		Unk		Not Reported
	Lactated Ringers			C		Unk		Not Reported
	Latanoprost			C		Unk		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Metoprolol Tartrate			C		Unk		Not Reported
	Metronidazole			C		Unk		Not Reported
	Modafinil			C		Unk		Not Reported
	Mometasone			C		Unk		Not Reported
	Formoterol			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported

	Potassium Chloride	C	Unk	Not Reported
	Sertraline	C	Unk	Not Reported
	Sodium Chloride 0.9%	C	Unk	Not Reported
	Vancomycin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848077	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468738		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Flomax [Tamsulosin Hydrochloride]			C		Unk		Not Reported
	Vitamin C [Ascorbic Acid]			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Benzonatate			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dipyridamole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Zestoretic			C		Unk		Not Reported
	Meropenem			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849181	DIRECT	Y	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Vomiting	Remdesivir Eua			S				Not Reported
	Convalescent Plasma			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849209	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Culture Positive; International Normalised Ratio Increased; Staphylococcal Infection	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Not Reported
	Warfarin			C				Not Reported
	Vancomycin			C				Not Reported
	Amlodipine			C				Not Reported
	Asprin			C				Not Reported
	Carvedilol			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levothyroxine			C				Not Reported
	Pravastatin			C				Not Reported
	Terazosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849214	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Oxybutin			C				Not Reported
	Losartan			C				Not Reported
	Enoxaparin			C				Not Reported
	Potassium			C				Not Reported
	Gabapentin			C				Not Reported
	Duloxetine			C				Not Reported

		Lorazepam			C					Not Reported
		Rocuronium			C					Not Reported
		Melatonin			C					Not Reported
		Levothyroxine			C					Not Reported
		Insulin Lispro			C					Not Reported
		Buspirone			C					Not Reported
		Amlodipine			C					Not Reported
		Prednisone			C					Not Reported
		Propofol			C					Not Reported
		Penicillin V Potassium			C					Not Reported
		Norepinephrine			C					Not Reported
		Hydromorphone			C					Not Reported
		Famotidine			C					Not Reported
		Lipase-Protease-Amylase			C					Not Reported
		Insulin Regular			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849220	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Betamethasone			C				Not Reported
	Docusate-Senna			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Metoprolol			C				Not Reported
	Polyethylene Glycol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849260	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Oxygen Saturation Decreased; Pulse Absent	Remdesivir			S	Intravenous drip			Gilead
	Plaquenil 200mg			C				Not Reported
	Prazosin 1mg			C				Not Reported
	Proventil Inhaler			C				Not Reported
	Aspirin 81mg			C				Not Reported

	Lactinex Granules	C	Not Reported
	Lasix 40mg/4ml Iv	C	Not Reported
	Lipitor 40mg	C	Not Reported
	Lovenox 40mg	C	Not Reported
	Heparin 25000 Unit/250ml	C	Not Reported
	Protonix	C	Not Reported
	Robitussin Ac Syrup	C	Not Reported
	Ascorbic Acid 500mg	C	Not Reported
	Vitamin D 2000 Units	C	Not Reported
	Zinc Sulfate 200mg	C	Not Reported
	Zoloft 100mg	C	Not Reported
	Zyloprim 100mg	C	Not Reported
	Propofol	C	Not Reported
	Vasostrict	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849266	DIRECT	Y	DE			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palliative Care; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849270	DIRECT	Y	DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir (200 Mg X 1 Dose Followed By 100 Mg Daily)			S				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Carvedilol			C				Not Reported
	Lovenox			C				Not Reported
	Ivig			C				Not Reported
	Losartan			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pyridostigmine			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849276	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palliative Care; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849282	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cells In Urine; Fungal Infection; Glomerular Filtration Rate Decreased; Renal Tubular Necrosis; Urine Analysis Abnormal; White Blood Cells Urine Positive	Remdesivir Eua			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir Eua			S	Intravenous drip			Gilead
	Vancomycin 1.25g Iv Q24hrs			C				Not Reported
	Vancomycin 1.25g Iv Q12hrs			C				Not Reported
	Vancomycin 1g Iv X One Dose			C				Not Reported
	Vancomycin 1g Iv X One Dose			C				Not Reported
	Zosyn 4.5g Iv X One Dose			C				Not Reported
	Zosyn 3.375g Iv Q8hrs Extended Infusion			C				Not Reported
	Midazolam Iv Infusion Continuous			C				Not Reported
	Insulin Iv Infusion Continuous			C				Not Reported
	Fentanyl Iv Infusion			C				Not Reported
	Clonidine 0.2mg Transdermal Patch Q 7 Days			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849287	DIRECT	Y	DE, OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Disease Progression; Hypoxia;	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

Myalgia; Pneumonia Staphylococcal; Pyrexia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849288	DIRECT	Y	DE			59 YR	Male	AFG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Bicarbonate Decreased; Blood Bilirubin Increased; Blood Creatinine Increased; Blood Glucose Decreased; Blood Ph Decreased; Blood Potassium Increased; Blood Sodium Increased; Blood Urea Increased; Cardio-Respiratory Arrest; Glomerular Filtration Rate Decreased; Haematocrit Decreased; Haemoglobin Decreased; Mean Cell Haemoglobin Concentration Decreased; Mean Cell Haemoglobin Decreased; Mean Platelet Volume Increased; Metabolic Acidosis; Oxygen Saturation Decreased; Pco2 Increased; Platelet Count Decreased; Po2 Decreased; Polychromasia; Protein Total Decreased; Red Blood Cell Count Decreased; Red Cell	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

Distribution Width Increased; Sepsis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849289	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849304	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous bolus		4 DAY	Gilead
	Actemra 600 Mg Iv Once			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849309	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Impairment; Therapy Interrupted	Remdesivir			S	Intravenous drip	Other Frequency:One Time;		Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Methylprednisolone			C				Not Reported
	Regular Insulin			C				Not Reported
	Cefepime			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Versed			C				Not Reported
	Propofol			C				Not Reported

		Heparin			C					Not Reported
		D5/Sodium Bicarbonate Drip			C					Not Reported
		Sodium Bicarbonate 50meq Push			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849315	DIRECT	Y	DE, OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir	Y		S	Intravenous bolus			Gilead
	Convalescent Plasna			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849320	DIRECT	Y	DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Cardiogenic Shock; General Physical Health Deterioration; Hypotension; Lethargy; Malaise; Pulmonary Embolism; Right Atrial Enlargement; Right Ventricular Dysfunction; Right Ventricular Enlargement; Vomiting	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading Dose;		Gilead
	Convalescent Plasma			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849324	DIRECT	Y	DS, OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Creatinine Renal Clearance Decreased;	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen 650 Mg			C				Not Reported
	Albuterol			C				Not Reported
	Azithromycin			C				Not Reported

Oliguria; Prerenal Failure; Therapy Interrupted	Colchicine	C	Not Reported
	Fentanyl	C	Not Reported
	Hydrocortisone 50 Mg Q8h	C	Not Reported
	Pantoprazole 40 Mg Iv	C	Not Reported
	Piperacillin Tazobactam	C	Not Reported
	Prednisone	C	Not Reported
	Tociluzumab 800 Mg	C	Not Reported
	Vancomycin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849330	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Dysphagia; End Stage Renal Disease; Failure To Thrive; Pneumonia Viral; Respiratory Failure	Remdesivir			S	Intravenous drip			Gilead
	Zosyn			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849357	DIRECT	Y	HO			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849363	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849368	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis; Renal Failure; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S				Gilead
	Simvastatin			C				Not Reported
	Melatonin			C				Not Reported
	Levothyroxine			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Insulin Regular			C				Not Reported
	Insulin Lispro			C				Not Reported
	Hydrophorphone			C				Not Reported
	Meropenem			C				Not Reported
	Prismassol			C				Not Reported
	Linezoid			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Lisinopril-Hydrochlorothiazide			C				Not Reported
	Diclofenac			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Glargine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849369	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Supraventricular Extrasystoles; Ventricular Tachycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849373	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen Prn			C				Not Reported
	Bisacodyl Supp Prn			C				Not Reported
	Chlorhexidine Po Bid			C				Not Reported
	Robitussin Dm Prn			C				Not Reported
	Heparin 7.500 U Subq Tid			C				Not Reported
	Melatonin Prn Insomnia			C				Not Reported
	Menthol Lozenge Prn			C				Not Reported
	Methocarbamol 750mg Po Bid Prn			C				Not Reported
	Bengay Cream Prn			C				Not Reported
	Solu-Medrol 40mg Iv Bid			C				Not Reported
	Bactroban Oint Nasal Bid			C				Not Reported
	Ns Iv Solution			C				Not Reported
	Zofran Po/Iv Prn			C				Not Reported
	Pantoprazole			C				Not Reported
	Miralax Daily Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849387	DIRECT	Y	OT			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849393	DIRECT	Y	DE			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Fentanyl Drip			C				Not Reported
	Heparin Drip			C				Not Reported
	Levopred Drip			C				Not Reported
	Rocuronium Drip			C				Not Reported

		Vasopressin Drip			C					Not Reported
		Versed Drip			C					Not Reported
		Tpn			C					Not Reported
		Mucomyst 600mg Bid Via Tube			C					Not Reported
		Ascobic Acid			C					Not Reported
		Cholecalciferol			C					Not Reported
		Docusate			C					Not Reported
		Regular Insulin			C					Not Reported
		Protonix			C					Not Reported
		Miralax			C					Not Reported
		Selenium			C					Not Reported
		Vitamin A			C					Not Reported
		Vitamin E			C					Not Reported
		Zinc Sulfate			C					Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
01-Jun-2020	17849399	DIRECT	Y	OT				52 YR	Male	USA
Preferred Term	**Product**		**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**		**Mfr**
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Therapy Interrupted	Remdesivir		Y		S	Intravenous (not otherwise specified)				Gilead
	Cefepime				C					Not Reported
	Hydrocortisone				C					Not Reported
	Lantus				C					Not Reported
	Humalog Slicing Scale				C					Not Reported
	Protonix				C					Not Reported
	Vancomycin				C					Not Reported
	Zinc Sulfate				C					Not Reported
	Fentanyl Drip				C					Not Reported
	Heparin Drip				C					Not Reported
	Norepinephrine Drip				C					Not Reported
	Propofol Drip				C					Not Reported
	Rucuronium Drip				C					Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
01-Jun-2020	17849407	DIRECT	Y					55 YR	Female	USA
Preferred Term	**Product**		**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**		**Mfr**

Blood Pressure Decreased	Remdesivir	S	Intravenous (not otherwise specified)		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17849442	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Dialysis; Oliguria; Renal Impairment; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17794570	EXPEDITED (15-DAY)		DE, HO, LT, OT	NL-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-037224		66 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Haematoma Muscle; Lactic Acidosis; Off Label Use; Renal Failure; Respiratory Failure; Subcutaneous Abscess	Apixaban			S	Unknown	Unk		Bristol Myers Squibb
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram, Qd		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd		Not Reported
	Nadroparine			S	Unknown	Unk		Not Reported
	Pravastatine [Pravastatin Sodium]			C	Unknown	Unk		Not Reported
	Metoclopramide			C	Unknown	Unk		Not Reported
	Nifedipine			C	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	Unk		Not Reported
	Oxycodone [Oxycodone Hydrochloride]			C	Unknown	Unk		Not Reported
	Fenoterol;Ipratropium			C	Unknown	Unk		Not Reported

	Cotrimaxazol	C	Unknown	Unk		Not Reported
	Valaciclovir	C	Unknown	Unk		Not Reported
	Allopurinol	C	Unknown	Unk		Not Reported
	Paracetamol	C	Unknown	Unk		Not Reported
	Pantoprazol [Pantoprazole]	C	Unknown	Unk		Not Reported
	Flucloxacillin	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849531	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849543	DIRECT	Y	DE			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17849845	DIRECT	Y	HO			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Thiamine			C				Not Reported
	Zinc			C				Not Reported

	Bumetanide			C					Not Reported
	Clonazepam			C					Not Reported
	Famotidine			C					Not Reported
	Insulin Lispro			C					Not Reported
	Dexmedetomidine			C					Not Reported
	Dobutamine			C					Not Reported
	Fentanyl			C					Not Reported
	Methylprednisolone			C					Not Reported
	Acetaminophen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850775	DIRECT	Y	OT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Alanine Aminotransferase Increased; Glomerular Filtration Rate Decreased; Rales	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Citalopram			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydroxyzine			C				Not Reported
	Lisinopril			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Miralax			C				Not Reported
	Sodium Chloride Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850817	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Povidone Iodine			C				Not Reported

		Potassium Chloride, Extended Release			C					Not Reported
		Simvastatin			C					Not Reported
		Insulin Lispro			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850823	DIRECT	Y	DS, HO, OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Haemodialysis	Remdesivir			S	Parenteral			Gilead
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850829	DIRECT	Y	DS, HO, OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased; Urine Output Decreased	Remdesivir			S	Parenteral			Not Reported
	Vancomycin			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850833	DIRECT	Y	HO			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850839	DIRECT	Y	DE, HO, OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Haemodialysis; Renal Impairment	Remdesivir		S	Parenteral	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850843	DIRECT	Y	DS, HO, OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased; Haemodialysis; Urine Output Decreased	Remdesivir			S	Parenteral			Gilead
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850847	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase	Remdesivir			S	Intravenous drip			Not Reported
	Vancomycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850883	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Musculoskeletal Stiffness	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Aspirin Chewable 81 Mg			C				Not Reported
	Gabapentin			C				Not Reported
	Magnesium Oxide			C				Not Reported

	Metoprolol Tartrate				C					Not Reported
	Pantoprazole				C					Not Reported
	Pravastatin				C					Not Reported
	Rivaroxaban				C					Not Reported
	Ropinirole				C					Not Reported
	Tamsulosin				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850888	DIRECT	Y	DE, DS, HO, OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Haemodialysis; Multiple Organ Dysfunction Syndrome; Renal Impairment; Respiratory Failure	Remdesivir			S	Parenteral			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850892	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medical Observation	Remdesivir			S	Parenteral			Gilead
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Zosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850895	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850901	DIRECT	Y				79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Allopurinol 100mg Po Daily			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Apixaban 5mg Po Bid			C				Not Reported
	Ascorbic Acid 250mg Po Daily			C				Not Reported
	Aspirin Ec 81mg Po Daily			C				Not Reported
	Bumetanide 1mg Po Daily			C				Not Reported
	Famotidine 40mg Po Daily			C				Not Reported
	Ferrous Sulfate 325mg Po Bid			C				Not Reported
	Gabapentin 300mg Po Bid			C				Not Reported
	Levothyroxine 100 Mcg Po Daily			C				Not Reported
	Lidocaine 5% Patch Td Daily			C				Not Reported
	Lisinopril 10mg Po Daily			C				Not Reported
	Multivitamin 1 Tablet Po Daily			C				Not Reported
	Pantoprazole 40mg Po Daily			C				Not Reported
	Acetaminophen 650mg Po Q6h Prn Fever			C				Not Reported
	Guaifenesin 200mg Po Q4h Prn Cough			C				Not Reported
	Iohexol 350mg Iodine/Ml Inj: Dose=75ml Once			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850905	DIRECT	Y	LT, OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Dehydration; Pulmonary Oedema; Renal Disorder	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:X1. Then 100mg/Day;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850908	DIRECT	Y	DE, OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cardiac Arrest; Hypoxia; Nausea; Respiratory Failure; Vomiting	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850912	DIRECT	Y	HO			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Amlodipine			C				Not Reported
	Dextromethorphan			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Heparin			C				Not Reported
	Lactated Ringers			C				Not Reported
	Sodium Chloride 0.9%			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850927	DIRECT	Y	OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850931	DIRECT	Y				28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Cholecalciferol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Methylprednisolone			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Famotidine			C				Not Reported
	Topiramate			C				Not Reported
	Vecuronium			C				Not Reported
	Thiamine			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850933	DIRECT	Y	DE, HO, LT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Pyrexia; Respiratory Distress	Emergency Use Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:X1 Loading Dose;		Gilead
	Emergency Use Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Hydralazine			C				Not Reported
	Imdur			C				Not Reported
	Ketorolac			C				Not Reported
	Levemir			C				Not Reported
	Linezolid			C				Not Reported
	Memantine			C				Not Reported
	Novolog			C				Not Reported

	Potassium Chloride	C		Not Reported
	Potassium Phosphate Sodium Phosphate	C		Not Reported
	Percocet	C		Not Reported
	Primidone	C		Not Reported
	Pyridoxine	C		Not Reported
	Vancomycin	C		Not Reported
	Vitamin D	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17850940	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Connection Issue; Drug Dose Omission By Device; Product Leakage; Product Supply Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17852138	EXPEDITED (15-DAY)		DE, HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000437			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Pancreatitis	Furosemide			S	Intravenous (not otherwise specified)	Unk		Validus
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Kardegic			C		Unk		Not Reported
	Coumadine			C		Unk		Not Reported
	Perfalgan			C		Unk		Not Reported
	Triatec /00885601/			C		Unk		Not Reported
	Piperacillin			C		Unk		Not Reported
	Cordarone			C		Unk		Not Reported
	Rovamycine /00074401/			C		Unk		Not Reported

	Cefotaxime	C	Unk		Not Reported
	Heparin Al	C	Unk		Not Reported
	Ciprofloxacin	C	Unk		Not Reported
	Tazobactam	C	Unk		Not Reported
	Solupred /00016217/	C	Unk		Not Reported
	Bisoce	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853588	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469405		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Brovana			C				Not Reported
	Anoro Ellipta			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Prednisone			C				Not Reported
	Insulin			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Atorvastatin			C				Not Reported
	Metformin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Rocephin [Ceftriaxone]			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853597	EXPEDITED (15-DAY)		DE, HO	US-GILEAD-2020-0469416		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; General Physical Condition	Remdesivir			S	Intravenous (not	200 Mg, Once		Gilead

Abnormal; Hypotension; Oxygen Consumption Decreased	Remdesivir	S	otherwise specified) Intravenous (not otherwise specified)	100 Mg, Qd			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17853613	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469516		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C		Unk		Not Reported
	Ipratropium			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Piperacillin / Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854398	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cough; Dyspnoea; Hypertension; Illness	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854534	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854539	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Condition Aggravated; Dialysis; General Physical Health Deterioration	Remdesivir	Y		S	Intravenous drip		2 DAY	Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854546	DIRECT	Y	HO			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854552	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported

		Omnipaque 350 Mg			C					Not Reported
		Vancomycin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854560	DIRECT	Y	DE			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Glomerular Filtration Rate Abnormal; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854566	DIRECT	Y	OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholecystitis; Cholelithiasis; Chronic Kidney Disease; Condition Aggravated; Hepatic Enzyme Increased; Renal Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Melatonin			C				Not Reported
	Insulin Regular			C				Not Reported
	Insulin Lispro			C				Not Reported
	Hydromorphone			C				Not Reported
	Famotidine			C				Not Reported
	Levothyroxine			C				Not Reported
	Atorvastatin			C				Not Reported
	Linezolid			C				Not Reported
	Insulin Glargine			C				Not Reported
	Cefepime			C				Not Reported
	Metolazone			C				Not Reported
	Insulin Isophane			C				Not Reported
	Bumetanide			C				Not Reported
	Losartan			C				Not Reported
	Metformin			C				Not Reported

		Metoprolol Succinate			C						Not Reported
		Pregabalin			C						Not Reported
		Liraglutide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854573	DIRECT	Y				56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Respiratory Arrest; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854578	DIRECT	Y	DE			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Morphine Drip			C				Not Reported
	Norepinepine Drip			C				Not Reported
	Rocuronium Drip			C				Not Reported
	Vasopressin Drip			C				Not Reported
	Versed Drip			C				Not Reported
	Phenylehprine Drip			C				Not Reported
	Tpn			C				Not Reported
	Vancomcyin			C				Not Reported
	Meropenem			C				Not Reported
	Humalog Sliding Scale			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Heparin For Crrt			C				Not Reported
	Selenium			C				Not Reported
	Vitamin E			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17854729	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855372	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg Vial			S	Intravenous (not otherwise specified)			Gilead
	Furosemide			C				Not Reported
	Lovenox			C				Not Reported
	Unasyn			C				Not Reported
	Protonix			C				Not Reported
	Metoprolol			C				Not Reported
	Keppra			C				Not Reported
	Fentanyl			C				Not Reported
	Versed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855700	EXPEDITED (15-DAY)			US-GILEAD-2020-0468459		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855745	DIRECT	Y				66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol			C				Not Reported
	Ipratropium			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Pantoprazole			C				Not Reported
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855748	DIRECT	Y	DS, HO, LT, OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ergocalciferol			C				Not Reported
	Heparin			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Ketamine			C				Not Reported
	Melatonin			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Rocuronium			C				Not Reported
	Succinylcholine			C				Not Reported

	Thiamine			C						Not Reported
	Vancomycin			C						Not Reported
	Zinc Sulfate			C						Not Reported
	Acetaminophen			C						Not Reported
	Albumin			C						Not Reported
	Insulin Regular			C						Not Reported
	Fentanyl			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856141	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0468702		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856201	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468990		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Covid-19; Respiratory Failure; Shock	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Insulin Regular Hm			C		Sliding Scale		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Vasopressin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856753	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469662		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bronchitis; Hypotension; Multiple Organ Dysfunction Syndrome; Oliguria; Pneumonia; Renal Impairment; Respiratory Failure; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Rocuronium			C				Not Reported
	Azithromycin			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Medrol [Methylprednisolone]			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Zosyn			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Versed			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Vasopressin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857107	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469610		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Renal Failure; Tachypnoea	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Aspirin (E.C.)			C		Unk		Not Reported
	Atorvastatin			C				Not Reported
	Benzonatate			C				Not Reported

	Normosol R	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Fentanyl	C	Unk	Not Reported
	Furosemide	C	Unk	Not Reported
	Guaifenesin/Codeine	C	Unk	Not Reported
	Heparin	C	Unk	Not Reported
	Hydrochlorothiazide	C	Unk	Not Reported
	Hydromorphone	C	Unk	Not Reported
	Insulin 2	C		Not Reported
	Labetalol	C	Unk	Not Reported
	Lactated Ringers	C	Unk	Not Reported
	Levothyroxine	C	Unk	Not Reported
	Lidocaine	C	Unk	Not Reported
	Lorazepam	C	Unk	Not Reported
	Magnesium Sulfate	C	Unk	Not Reported
	Morphine	C	Unk	Not Reported
	Convalescent Plasma	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857141	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469657		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Hypoxia; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Once		Gilead
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Carbidopa + Levodopa			C				Not Reported
	Donepezil			C				Not Reported
	Enoxaparin			C				Not Reported

		Lispro Insulin			C						Not Reported
		Metoprolol			C						Not Reported
		Montelukast			C						Not Reported
		Solifenacin			C						Not Reported
		Acetaminophen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857144	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469659		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram Per Millilitre, Once		Gilead
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported
	Nimbex [Cisatracurium Besilate]			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Insulin			C				Not Reported
	Heparin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857171	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469603		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Colace			C				Not Reported
	Eliquis			C				Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Pepcid [Famotidine]			C				Not Reported
	Miralax			C				Not Reported
	Seroquel			C				Not Reported

	Singulair			C						Not Reported
	Zofran [Ondansetron]			C						Not Reported
	Acetaminophen			C						Not Reported
	Piperacillin/Tazobactam			C						Not Reported
	Azithromycin			C						Not Reported
	Diclofenac			C						Not Reported
	Propofol			C						Not Reported
	Norepinephrine			C						Not Reported
	Fentanyl			C						Not Reported
	Dexmedetomidine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17857185	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469616		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858737	DIRECT	Y	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S				Gilead
	Furosemide			C				Not Reported
	Potassium Chloride			C				Not Reported
	Lactulose			C				Not Reported
	Divalproex			C				Not Reported
	Cholecalciferol			C				Not Reported
	Risperidone			C				Not Reported
	Ramelteon			C				Not Reported
	Clonazepam			C				Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C				Not Reported
	Piperacillin Tazobactam			C				Not Reported
	Lamotrigine			C				Not Reported
	Tamsulosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858747	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Aripiprazole			C				Not Reported
	Famotidine			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Regular			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Norepinephrine			C				Not Reported
	Potassium			C				Not Reported
	Propofol			C				Not Reported
	Melatonin			C				Not Reported
	Bupropion			C				Not Reported
	Cetirizine			C				Not Reported
	Gababpentin			C				Not Reported
	Prednisone			C				Not Reported
	Sertraline			C				Not Reported
	Trazodone			C				Not Reported
	Ocrelizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858915	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Therapy Interrupted	Remdesivir			S	Intravenous drip			Gilead
	Dilaudid Drip			C				Not Reported
	Propofol Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858934	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Chills; Heart Rate Decreased; Hyperhidrosis; Infusion Related Reaction; Tremor	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Albuterol (Proventil) Nebulizer Solution			C				Not Reported
	Azithromycin (Zithromax) 500 Mg In Ns Ivpb			C				Not Reported
	Benzonatate (Tessalon) Capsule			C				Not Reported
	Ceftriaxone (Rocephin) 1 G In Ns Ivpb			C				Not Reported
	Heparin, Porcine Injection 7,500 Units Subq Tid			C				Not Reported
	Ipratropium-Albuterol (Combivent) Inhaler			C				Not Reported
	Methylprednisolone *Pf* (Solu-Medrol) Injection 40 Mg			C				Not Reported
	Morphine Injection			C				Not Reported
	Ns			C				Not Reported
	Ondansetron			C				Not Reported
	Pravastatin			C				Not Reported
	Thiamine 100mg Tablet			C				Not Reported
	Iohexol (Omnipaque) 350 Mg Iodine/Ml Injection			C				Not Reported
	Quetiapine (Seroquel) Tablet 200 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858974	DIRECT	Y	OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Amiodarone			C				Not Reported
	Zosyn			C				Not Reported

		Methylprednisolone			C						Not Reported
		Fentanyl			C						Not Reported
		Norepinephrine			C						Not Reported
		Propofol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858982	DIRECT	Y	HO, OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir Injection	Y		S	Intravenous bolus			Gilead
	Furosemide			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17858990	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen (Prn)			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Atropine			C				Not Reported
	Benzonatate			C				Not Reported
	Bumetanide			C				Not Reported
	D50w (Prn)			C				Not Reported
	Doxycycline --Intravenous			C				Not Reported
	Epinephrine--Intravenous Drip			C				Not Reported
	Hydromorphone--Intravenous Drip			C				Not Reported
	Insulin Glargine			C				Not Reported
	Regular Insulin Drip/Sliding Scale			C				Not Reported
	Lubricant Eye Ointment (And Also Natural Tears Drops)			C				Not Reported
	Methylprednisolone Sodium			C				Not Reported

	Succinate		
	Multivitamin Tablet	C	Not Reported
	Nebivolol	C	Not Reported
	Pantoprazole	C	Not Reported
	Propofol--Intravenous Drip	C	Not Reported
	Rocuronium	C	Not Reported
	Zosyn	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17859011	DIRECT	Y	DE			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Cough; Epistaxis; Haemoptysis; Hypotension; Pulseless Electrical Activity; Respiratory Arrest; Retching	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Rivaroxaban			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17859017	DIRECT	Y	DE			99 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Pressure Decreased; Mental Status Changes; Somnolence	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17859024	DIRECT	Y	OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Anuria; Blood Creatinine Increased; Cardiac Dysfunction; Dialysis; International	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead

Normalised Ratio Increased; Renal Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17859029	DIRECT	Y	OT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Ulcer Haemorrhage; Haemoglobin Decreased; Melaena	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17859036	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Hydrocodone/Acetaminophen			C				Not Reported
	0.9% Sodium Chloride			C				Not Reported
	Butalbital-Acetaminophen-Caffeine			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17859043	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Enoxaparin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17859048	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Hypoperfusion; Jugular Vein Thrombosis; Pneumonia; Sepsis	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17793631	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0466952		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Pulseless Electrical Activity; Ventricular Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860016	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Drug Administration Rate; Infusion Site Haemorrhage; Infusion Site Pain	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860021	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Kaletra			C				Not Reported
	Actemra			C				Not Reported
	Zithromax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860075	DIRECT	Y				48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860079	DIRECT	Y	OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Haemodialysis	Remdesivir	Y		S	Intravenous drip			Gilead
	Ascorbic Acid			C				Not Reported
	Cefepime			C				Not Reported
	Cholecalciferol			C				Not Reported
	Enoxaparin			C				Not Reported
	Fluconazole			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Melatonin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Regular			C				Not Reported

		Norepinephrine			C					Not Reported
		Potassium Chloride			C					Not Reported
		Sodium Phosphate			C					Not Reported
		Succinylcholine			C					Not Reported
		Midazolam			C					Not Reported
		Metoprolol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860084	DIRECT	Y	DE			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Dyspnoea; Hypoxia	Remdesivir			S	Parenteral			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860088	DIRECT	Y	OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous drip			Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860095	DIRECT		DE			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple-Drug Resistance; Pneumonia	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860100	DIRECT	Y	HO			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Alanine Aminotransferase Decreased; Covid-19 Pneumonia; Nephropathy Toxic; Renal Impairment; Renal Ischaemia; Respiratory Failure; Septic Shock	Remdesivir	Y	S	Intravenous drip	Gilead
	Ceftriaxone		C		Not Reported
	Azithromycin		C		Not Reported
	Norepinephrine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860412	EXPEDITED (15-DAY)		LT	US-ACS-001698		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sepsis	Meropenem			S	Unknown			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	From 01-Apr-2020 To 09-Apr-2020, The Patient Received Remdesivir 100 Mg Iv		Not Reported
	Chloroquine			C	Unknown			Not Reported
	Metoprolol Tartrate			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Albuterol/Ipratropium			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported
	Diazepam			C	Unknown			Not Reported
	Vancomycin			C	Unknown			Not Reported
	Propofol			C	Unknown			Not Reported
	Norepinephrine			C	Unknown			Not Reported
	Phenylephrine			C	Unknown			Not Reported
	Digoxin			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Diltiazem			C	Unknown			Not Reported

		Fluoxetine Hydrochloride			C	Unknown			Not Reported
		Insulin			C	Unknown			Not Reported
		Levothyroxine			C	Unknown			Not Reported
		Amiodarone			C	Unknown			Not Reported
		Bupropion Hydrochloride			C	Unknown			Not Reported
		Cefazolin			C	Unknown			Not Reported
		Enoxaparin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860990	DIRECT	Y	OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Hydromorphone			C				Not Reported
	Propofol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Epoprostenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860994	DIRECT	Y	OT			90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Lethargy; Mechanical Ventilation; Mental Status Changes; Walking Aid User	Remdesivir			S	Intravenous drip			Gilead
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Cholecalciferol			C				Not Reported
	Codeine/Guaifenesin			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported

		Fentanyl			C						Not Reported
		Furosemide			C						Not Reported
		Hydralazine			C						Not Reported
		Insulin			C						Not Reported
		Levetiracetam			C						Not Reported
		Levothyroxine			C						Not Reported
		Multivitamin			C						Not Reported
		Pantoprazole			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17860999	DIRECT	Y	DE			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Antibiotic Therapy; Renal Replacement Therapy	Remdesivir Under Emergency Use Authorization	Y		S	Intravesical			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861003	DIRECT	Y	HO			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Disorder	Remdesivir	Y		S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Epoprostenol			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin Drip			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861008	DIRECT		OT			30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone 60mg Iv Q8h			C				Not Reported
	Methylprednisolone 40mg Iv Q8h			C				Not Reported
	Tocilizumab 400mg Ivpd			C				Not Reported
	Acetaminophen 1000mg Ivpb Q6h Prn			C				Not Reported
	Oxycodone/Acetaminophen 5mg/325mg Q6h Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861033	DIRECT	Y	DE			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Arrest	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetamenophen			C				Not Reported
	Amlodepine			C				Not Reported
	Atorvastatin			C				Not Reported
	Bumetanide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dabigatran			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Guaifenesin			C				Not Reported
	Lantus Insulin			C				Not Reported
	Novolog Insulin			C				Not Reported
	Levothyroxine			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Senna S			C				Not Reported
	Tiotropium			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861039	DIRECT					48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861907	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0469837		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Acute Kidney Injury; Blood Creatinine Increased; Cardiovascular Disorder; Gastrointestinal Haemorrhage; Glomerular Filtration Rate Decreased; Hyperkalaemia; Hypovolaemic Shock; Metabolic Acidosis; Shock Haemorrhagic	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Protonix [Omeprazole]			C		Unk		Not Reported
	Atarax [Alprazolam]			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Ketamine			C		Unk		Not Reported
	Versed			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17862396	EXPEDITED (15-DAY)			US-GILEAD-2020-0469055		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Dextrose Water			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17862427	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0468936		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dyspnoea; Feeling Hot	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17862432	EXPEDITED (15-DAY)			US-GILEAD-2020-0468996			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863082	EXPEDITED (15-DAY)			US-GILEAD-2020-0469009		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Dispensing Error; Product Administration Error; Product Dispensing Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Carvedilol			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Hydrocortisone			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863105	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469189		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Renal Impairment	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Unk, Qd		Gilead
	Acetaminophen	C				Not Reported
	Albuterol;Ipratropium	C				Not Reported
	Apixaban	C				Not Reported
	Dexmedetomidine	C				Not Reported
	Baclofen	C				Not Reported
	Cefepime	C				Not Reported
	Ceftriaxone	C				Not Reported
	Doxycycline	C				Not Reported
	Midazolam	C				Not Reported
	Ferrous Sulfate	C				Not Reported
	Fluconazole	C				Not Reported
	Folic Acid	C				Not Reported
	Furosemide	C				Not Reported
	Heparin	C				Not Reported
	Meropenem	C				Not Reported
	Tocilizumab	C				Not Reported
	Vancomycin	C				Not Reported
	Norepinephrine	C				Not Reported
	Propofol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863108	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0469179		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Metoprolol			C				Not Reported
	Potassium Bicarbonate;Sodium			C				Not Reported

		Phosphate									
		Potassium Chloride			C						Not Reported
		Vancomycin			C						Not Reported
		Acetaminophen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863182	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469222		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Piperacillin+Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Fluconazole			C				Not Reported
	Fluticasone			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levothyroxine			C				Not Reported
	Senna [Senna Alexandrina Leaf]			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Sodium Chloride			C				Not Reported
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Iopamidol			C				Not Reported
	Ondansetron			C				Not Reported
	Promethazine			C				Not Reported
	Codeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17863307	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470071		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

Prazosin	C	Unk	Not Reported
Proventil [Salbutamol]	C	Unk	Not Reported
Aspirin [Acetylsalicylic Acid]	C	Unk	Not Reported
Lactinex [Lactobacillus Acidophilus]	C	Unk	Not Reported
Lasix [Furosemide]	C	Unk	Not Reported
Lipitor [Atorvastatin]	C	Unk	Not Reported
Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Protonix [Omeprazole]	C	Unk	Not Reported
Robitussin A C	C	Unk	Not Reported
Ascorbic Acid	C	Unk	Not Reported
Vitamin D [Colecalciferol]	C	Unk	Not Reported
Zinc Sulfate	C	Unk	Not Reported
Zoloft	C	Unk	Not Reported
Zyloprim	C	Unk	Not Reported
Propofol	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864171	DIRECT	Y	OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Tociluzimab			C				Not Reported
	Colchine			C				Not Reported
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864177	DIRECT	Y	HO			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous drip		Gilead
	Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864180	DIRECT	Y				77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Midazolam			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Famotidine			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864182	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864201	DIRECT	Y	HO			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Haemodialysis	Remdesivir	Y	S	Intravenous bolus	Other Frequency:Once;	Gilead
	Acetaminophen		C			Not Reported
	Alprazolam		C			Not Reported
	Azithromycin		C			Not Reported
	Bupropion		C			Not Reported
	Calcium Gluconate		C			Not Reported
	Enoxaparin		C			Not Reported
	Famotidine		C			Not Reported
	Fentanyl		C			Not Reported
	Gabapentin		C			Not Reported
	Hydroxychloroquine		C			Not Reported
	Iopamidol		C			Not Reported
	Losartan		C			Not Reported
	Methylprednisolone		C			Not Reported
	Norepinephrine		C			Not Reported
	Piperacillin/Tazobactam		C			Not Reported
	Propofol		C			Not Reported
	Rocuronium		C			Not Reported
	Vancomycin		C			Not Reported
	Vecuronium		C			Not Reported
	Venlafaxine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864223	DIRECT	Y	LT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864252	DIRECT	Y	DE			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus	Other Frequency:X1;		Gilead

		Remdesivir			S	Intravenous bolus				Gilead
		Hydroxychloroquin 200mg Po Bid			C					Not Reported
		Actemra 400mg X1			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864258	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864265	DIRECT	Y	DE, HO			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; General Physical Health Deterioration; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous drip			Gilead
	Levophed			C				Not Reported
	Neo-Synephrine			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Versed Drip			C				Not Reported
	Nimbex Drip			C				Not Reported
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Precedex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864269	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Increased	Remdesivir	Y		S				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Midazolam Infusion			C				Not Reported

	Propofol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864279	DIRECT	Y	OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Creatinine Renal Clearance Decreased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864306	DIRECT	Y				25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17864803	DIRECT	Y	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir For Injection 100mg/Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Zinc			C				Not Reported
	Pantoprazole			C				Not Reported
	Meropenem			C				Not Reported
	Levothyroxine			C				Not Reported
	Levetiracetam			C				Not Reported
	Hydrocortisone			C				Not Reported
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Cipro			C				Not Reported
	Azithromycin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Dopamine			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865473	DIRECT	Y	OT			28 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Bilirubin Conjugated Abnormal	Remdesivir			S	Intravenous drip			Gilead
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Cisatracurium Drip			C				Not Reported
	Sennosides 5 Ml			C				Not Reported
	Docusate 50 Mg			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Epoprostenol Inhaled			C				Not Reported
	Famotidine 20 Mg			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Furosemide 40 Mg			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Nph			C				Not Reported
	Ketamine Drip			C				Not Reported
	Methylprednisone 60 Mg			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Zosyn 4.5 Grams			C				Not Reported
	Propofol Drip			C				Not Reported
	Timolol Eye Drop			C				Not Reported
	Vancomycin 1.5 Gram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865479	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865482	DIRECT	Y				29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Device Delivery System Issue	Remdesivir 100mg Iv In 100ml Ns	Y		S	Intravenous drip				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865487	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiac Arrest	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865494	DIRECT	Y	DE, LT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Infarction; International Normalised Ratio Increased; Miosis; Respiratory Failure; Thrombocytopenia; Troponin Increased; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Norepinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Succinylcholine			C				Not Reported
	Argatroban			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865506	DIRECT	Y	DE			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Amiodarone Drip			C				Not Reported
	Cefepime 1g Iv Q24h			C				Not Reported

Creatinine Increased; Cardiac Arrest; Circulatory Collapse; International Normalised Ratio Increased	Norepinephrine Drip			C					Not Reported
	Phytonadione 10 Mg Sc			C					Not Reported
	Propofol Drip			C					Not Reported
	Vancomycin 1g Iv Q12h			C					Not Reported
	Vasopressin Drip			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865510	DIRECT	Y	DE, OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Intravascular Coagulation; Dyspnoea; Pulmonary Embolism; Shock	Remdesivir			S	Intravenous drip	Other Frequency:Once-Loading Dose;		Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Convalescent Plasma			C				Not Reported
	Doxycycline			C				Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported
	Docusate Sodium			C				Not Reported
	Donepezil			C				Not Reported
	Enoxaparin			C				Not Reported
	Fluoxetine			C				Not Reported
	Melatonin			C				Not Reported
	Omeprazole			C				Not Reported
	Potassium Cholride			C				Not Reported
	Propofol			C				Not Reported
	Risperidone			C				Not Reported
	Senna Tablet			C				Not Reported
	Quetiapine			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Etomidate			C				Not Reported
	Succinylcholine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865514	DIRECT		OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypokalaemia	Remdesivir			S	Intravenous (not otherwise specified)				Not Reported
	Furosemide 20mg Ivp X1			C					Not Reported
	Furosemide 40mg Ivp X4			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865519	DIRECT		OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypophosphataemia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Furosemide 20mg Ivp X1			C				Not Reported
	Furosemide 40mg Ivp X4			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865524	DIRECT		OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S				Not Reported
	Acetaminophen 650mg Q4h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865547	DIRECT	Y				40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Disease Progression	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Vancomycin Ivpb			C				Not Reported
	Tocilizumab Ivpb			C				Not Reported
	Merrem Ivpb			C				Not Reported
	Azithromycin Ivpb			C				Not Reported
	Cefepime Ivpb			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865589	DIRECT		OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin 750mg Iv Once			C				Not Reported
	Vancomycin 1g Iv Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865594	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Aspirin 81mg Tab Po Daily			C				Not Reported
	Bumetanide 1mg Po Bid			C				Not Reported
	Carvedilol 25mg Po Bid			C				Not Reported
	Clopidogrel 75mg Po Daily			C				Not Reported
	Isosorbide Mononitrate 30mg Po Daily			C				Not Reported
	Montelukast 10mg Po Daily			C				Not Reported
	Pantoprazole 40mg Po Daily			C				Not Reported
	Pregabalin 75mg Po Tid			C				Not Reported
	Tramadol 50mg Po Q6h Prn Pain			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865599	DIRECT		OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukocytosis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17865627	DIRECT		DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Respiratory Arrest; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen 650mg Q4h Prn			C				Not Reported
	Insulin Human Regular Sliding Scale			C				Not Reported
	Norepinephrine Iv Drip			C				Not Reported
	Rocuronium 50mg Ivp X1			C				Not Reported
	Clonazepam 0.5mg Q8h			C				Not Reported
	Valproic Acid 125mg Q6h			C				Not Reported
	Atorvastatin 10mg Daily			C				Not Reported
	Levothyroxine 25mcg Daily			C				Not Reported
	Famotidine 20mg Q12h			C				Not Reported
	Enoxaparin 80mg Q12h			C				Not Reported
	Piperacillin/Tazobactam 3.375g Iv Q6h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866073	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Respiratory Depression	Remdesivir			S	Intravenous bolus			Gilead
	Propofol			S	Intravenous drip	Other Frequency:50-75mcg/Kg/Min;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866082	DIRECT	Y	OT			94 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Creatinine Renal Clearance Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866086	DIRECT		OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Function Test Abnormal; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866090	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Reaction	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866091	DIRECT		OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Norepinephrine Iv Drip			C				Not Reported
	Fentanyl Iv Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866098	DIRECT		HO			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Hepatitis; International Normalised Ratio Increased; Ischaemic Hepatitis; Liver Function	Remdesivir			S				Gilead
	Crestor			C				Not Reported
	Apixaban			C				Not Reported

Test Increased;
Rhabdomyolysis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866101	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lacunar Infarction; Seizure	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866105	DIRECT	Y	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866451	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0469160		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Myalgia; Rash Papular	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866498	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470010		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C				Not Reported

	Atorvastatin	C	Not Reported
	Carvedilol	C	Not Reported
	Lovenox [Enoxaparin Sodium]	C	Not Reported
	Losartan	C	Not Reported
	Methylprednisolone	C	Not Reported
	Pyridostigmine	C	Not Reported
	Piperacillin/Tazobactam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866546	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470050		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Nausea	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17866936	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469248		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Tremor	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Lantus			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868108	EXPEDITED (15-DAY)			US-GILEAD-2020-0469266		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue	Remdesivir			S	Unknown	200 Mg		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868192	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469449		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Budesonide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate;Senna			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Glargine			C				Not Reported
	Linagliptin			C				Not Reported
	Lisinopril			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol 3350			C				Not Reported
	Selinexor			C				Not Reported
	Tramadol			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868685	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Shock	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen Suppositories			C				Not Reported

			Acetaminophen Oral Tablets		C				Not Reported
			Acetylcysteine Po		C				Not Reported
			Albuterol Inhaler		C				Not Reported
			Aspirin		C				Not Reported
			Azithromycin		C				Not Reported
			Ceftriaxone		C				Not Reported
			D50w Prn Hypoglycemia		C				Not Reported
			Enoxaparin		C				Not Reported
			Etomidate (1 Dose For Intubation)		C				Not Reported
			Hydromorphone Drip		C				Not Reported
			Insulin Lispro--Sliding Scale		C				Not Reported
			Ipratropium Inhaler		C				Not Reported
			Methylprednisolone Sodium Succinate (X 1 Dose)		C				Not Reported
			Propofol Drip		C				Not Reported
			Rocuronium (1 Dose For Intubation)		C				Not Reported
			Sodium Chloride Drip		C				Not Reported
			Zosyn 3.375 G Iv		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868686	DIRECT	Y	LT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S				Not Reported
	Heparin			C				Not Reported
	Azithromycin			C				Not Reported
	Norepinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Midazolam			C				Not Reported
	Cefepime			C				Not Reported
	Hydromorphone			C				Not Reported
	Bisacodyl			C				Not Reported
	Vasopressin			C				Not Reported
	Propofol			C				Not Reported
	Ipratropium-Albuterol			C				Not Reported
	Acetylcysteine			C				Not Reported
	Insulin Regular			C				Not Reported
	Hydrocortisone Sodium			C				Not Reported

	Succinate									
	Famotidine			C						Not Reported
	Albuterol			C						Not Reported
	Perflutren Lipid Microspheres			C						Not Reported
	Chlorhexidine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868688	DIRECT	Y	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hyperhidrosis	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868690	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Calcium Gluconate			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone			C				Not Reported
	Phytonadione			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopression			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868691	DIRECT	Y	DS			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead
	Fluconazole			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Lisinopril			C				Not Reported

Amlodipine	C		Not Reported
Ferrous Sulfate	C		Not Reported
Omeprazole	C		Not Reported
Hydrocodone/Acetaminophen	C		Not Reported
Cyanocabalamin	C		Not Reported
Multivitamin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868692	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Respiratory Failure; Shock	Remdesivir Eua			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868694	DIRECT	Y	HO			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Renal Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868695	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868696	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Hepatic Enzyme Increased	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17868697	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiac Arrest	Remdesivir			S	Intravenous bolus	Other Frequency:Once Loading Dose;	1 DAY	Gilead
	Acetaminophen			C				Not Reported
	Artificial Tears			C				Not Reported
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Cholecalciferol			C				Not Reported
	Desmopressin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Nph			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17870105	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia; Respiratory Failure	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17870709	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19 Pneumonia	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17870830	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Areflexia; Cardiac Arrest; Condition Aggravated; Hypotension; Miosis; Nodal Rhythm; Pulmonary Arterial Pressure Increased; Pulmonary Fibrosis; Pulse Absent; Respiratory Failure; Right Ventricular Dilatation; Right Ventricular Failure; Sinus Bradycardia; Unresponsive To Stimuli	Remdesivir (Eua) (Remdesvir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin (Vancomycin Hcl 1gm/Vil Inj)			S	Intravenous (not otherwise specified)	Other Strength:1 Gm/Vil;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17870880	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Ammonia Increased; Aspartate Aminotransferase Increased; Atrial Fibrillation; Blood Lactic Acid Increased; Body Temperature Increased; Candida Test Positive; Chest Pain; Covid-19	Remdesivir			S				Not Reported
	Pantoprazole 40mg			S				Not Reported
	Atorvastatin 40mg			S				Not Reported
	Albuterol Neds			C				Not Reported
	Albumin			C				Not Reported
	Thiamine 100mg			C				Not Reported
	Furosemide 20mg			C		Other Route:Iv		Not Reported
	Lantus			C				Not Reported
	Multivitamin With Minerals			C				Not Reported

Pneumonia; Fluid Overload; Haemodynamic Instability; Hypotension; Interleukin Level Increased; Lung Opacity; Metabolic Acidosis; Oxygen Saturation Decreased; Renal Failure; Septic Shock

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2020	17871070	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Oxygen Saturation Decreased; Therapy Interrupted	Remdesivir 200mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead
	Bupropion 300mg 24 Hour Release Tablet			C	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Azltromycin			C				Not Reported
	Benzocaine-Menthol Lozenge			C				Not Reported
	Bisacodyl			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Gaulfensin			C				Not Reported
	Hydromorphone			C				Not Reported
	Melatonin			C				Not Reported
	Midazolam			C				Not Reported
	Noreplenphrine			C				Not Reported
	Nystalin			C				Not Reported
	Topical Powder			C				Not Reported
	Ondanestron			C				Not Reported
	Polyethylene Gylcol			C				Not Reported
	Potassium Bicarbonate-Citric			C				Not Reported

	Acid Effervescent			
	Propofol	C		Not Reported
	Senna (Senokot)	C		Not Reported
	Sertraline	C		Not Reported
	Temazepam	C		Not Reported
	Trazodone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868624	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469292		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dialysis; Off Label Use	Remdesivir			S	Unknown	50 Mg		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868698	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868699	DIRECT	Y	HO			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Chest X-Ray Abnormal; Chills; Dyspnoea; Heart Rate Increased; Infusion Related Reaction; Leukocytosis; Pyrexia	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Iv Pantoprazole 40mg			C				Not Reported
	Iv Lactated Ringers			C				Not Reported
	Humalog Sliding Scale Insulin			C				Not Reported
	Iv Covid-19 Convalescent Plasma			C				Not Reported
	Po Acetaminophen 650mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868700	DIRECT	Y	LT, OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Increased; Renal Disorder	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868701	DIRECT	Y	LT, OT			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Cholecalciferol 2000 Units Daily			C				Not Reported
	Melatonin 6 Mg Hs			C				Not Reported
	Atorvastatin 40 Mg Daily At 6pm			C				Not Reported
	Methylprednisolone 60 Mg Iv Q6h			C				Not Reported
	Enoxaparin 40 Mg Sq Q12h			C				Not Reported
	Humalog Sliding Scale			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868702	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir	Y		S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2020	17868703	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Alkaline Phosphatase Increased; General Physical Health Deterioration; Hypoxia; Liver Function Test Abnormal	Remdesivir	S	Intravenous bolus		Gilead
	Famotidine	C			Not Reported
	Heparin	C			Not Reported
	Meropenem	C			Not Reported
	Metoprolol	C			Not Reported
	Sodium Chloride	C			Not Reported
	Tolvaptan	C			Not Reported
	Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17869696	DIRECT	Y	OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17869704	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17869707	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus		5 DAY	Gilead
	Vasopressin			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Fentanyl			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Miratazepine			C				Not Reported
	Buspirone			C				Not Reported

	Bisacodyl			C					Not Reported
	Citalopram			C					Not Reported
	Cholecalciferol			C					Not Reported
	Vancomycin			C					Not Reported
	Cefepime			C					Not Reported
	Diltiazem			C					Not Reported
	Heparin			C					Not Reported
	Insulin			C					Not Reported
	Magnesium Oxide			C					Not Reported
	Oxycodone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17869710	DIRECT	Y	OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemodialysis; Metabolic Acidosis; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			C				Not Reported
	Anakinra			C				Not Reported
	Colchicine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2020	17869716	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Creatinine Renal Clearance Decreased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17818529	EXPEDITED (15-DAY)		DE, LT	US-GILEAD-2020-0468184		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Cefepime			C					Not Reported
	Ascorbic Acid			C					Not Reported
	Thiamine			C					Not Reported
	Doxycycline			C					Not Reported
	Methylprednisolone			C					Not Reported
	Pantoprazole			C					Not Reported
	Sertraline A			C					Not Reported
	Tamsulosin			C					Not Reported
	Zinc			C					Not Reported
	Ipratropium			C					Not Reported
	Enoxaparin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17856716	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469671		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fluoxetine			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Hydroxyzine			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871341	DIRECT	Y				83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)				Gilead
	Piperacillin-Tazobactam			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871346	DIRECT	Y	HO			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Amlodipine 5 Mg			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871365	DIRECT	Y				76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error; Wrong Technique In Product Usage Process	Remdesivir Eua			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871387	DIRECT	Y	DE, OT			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Tocilizumab			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871406	DIRECT	Y	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypotension; Ischaemic Hepatitis; Pneumonia Bacterial	Remdesivir				S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871437	DIRECT	Y				37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip		4 DAY	Gilead
	Tocilizumab			C				Not Reported
	Azithromycin			C				Not Reported
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871442	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871448	DIRECT	Y	OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Decreased	Remdesivir Eua			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871461	DIRECT	Y	DE			90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dehydration; Disease Progression; Hypoxia; Pain; Renal Failure	Remdesivir	Y	S	Intravenous (not otherwise specified)		Gilead
	Enoxaparin		C			Not Reported
	Lisinopril		C			Not Reported
	Metoprolol		C			Not Reported
	Pantoprazole		C			Not Reported
	Zosyn		C			Not Reported
	Pregabalin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17871973	DIRECT	Y	DE			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir 100mg Iv			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C				Not Reported
	Enoxaparin			C				Not Reported
	Levothyroxine			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872168	DIRECT	Y	DE			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospice Care	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872171	DIRECT	Y				37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation	Remdesivir	Y		S	Intravenous (not		2 DAY	Gilead

Error; Product Preparation Issue	otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872244	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Gilead
	Enoxaparin			C				Not Reported
	Dopamine/D5w			C				Not Reported
	Acetaminophen			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Ondansetron			C				Not Reported
	Sodium Cl Flush			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Etomidate			C				Not Reported
	Furosemide			C				Not Reported
	Lactated Ringers			C				Not Reported
	Lidocaine			C				Not Reported
	Midazolam			C				Not Reported
	Pantoprazole			C				Not Reported
	Potassium			C				Not Reported
	Azithromycin			C				Not Reported
	Hydromorphone			C				Not Reported
	Fentanyl			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872250	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Product Preparation Error; Wrong Product Administered	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872251	DIRECT	Y	DE			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospice Care	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872254	DIRECT	Y	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872258	DIRECT	Y	DE			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872280	DIRECT	Y				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Product Preparation Error; Wrong Product Administered	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872285	DIRECT	Y				47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Product Preparation Error; Wrong Product Administered	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872288	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Issue	Remdesivir	Y		S			1 DAY	Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872289	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872290	DIRECT	Y				56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872293	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872296	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872300	DIRECT	Y				27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872303	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872307	DIRECT	Y				77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872312	DIRECT	Y				79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872315	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17872366	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469297		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Ceftriaxone			C				Not Reported
	Dobutamine			C				Not Reported
	Doxycycline 3ddd			C				Not Reported

	Enoxaparin Becat				C					Not Reported
	Famotidine				C					Not Reported
	Fentanyl				C					Not Reported
	Hydrocortisone				C					Not Reported
	Midazolam				C					Not Reported
	Norepinephrine				C					Not Reported
	Phenylephrine				C					Not Reported
	Propofol				C					Not Reported
	Sodium Bicarbonate				C					Not Reported
	Vasopressin				C					Not Reported
	Digoxin				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17873015	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469646		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17873022	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469641		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk Unk, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17873048	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0469609		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Sertraline			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported

	Enoxaparin			C		Unk				Not Reported
	Ketorolac			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17873100	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469628		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874653	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiomyopathy; Transaminases Decreased	Remdesivir Solution (Emergency Use Authorization)			S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874657	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874659	DIRECT		HO			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Nephropathy Toxic	Remdesivir	S	Intravenous bolus	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874673	DIRECT	Y				26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Interaction; Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Azithromycin 500 Mg Po Daily			C				Not Reported
	Ceftriaxone 1 Gram Iv Q24h			C				Not Reported
	Dextromethorphan 60 Mg Po Q12h			C				Not Reported
	Enoxaparin 60 Mg Q12h			C				Not Reported
	Guaifenesin Er 600 Mg Po Bid			C				Not Reported
	Methylprednisolone 20 Mg Iv Q6h			C				Not Reported
	Acetaminophen/Hydrocodone 5/235 1 Tab Q4h Prn Pain			C				Not Reported
	Alprazolam 0.5 Mg Q8h Prn Anziety			C				Not Reported
	Benzonatte 100 Mg Po Tid Prn Cough			C				Not Reported
	Codeine-Guaifenesin 10-100 Mg Po Q4h Prn Cough			C				Not Reported
	Dexmedetomidine 400 Mcg At 0.2 Mcg/Kg/Hr Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874677	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Acetazolamide Extended Release			C				Not Reported
	Atorvastatin 10 Mg			C				Not Reported
	Ceftriaxone 1gm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874681	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874686	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Inj			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874702	DIRECT	Y	DE			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bacterial Infection; Blood Creatinine Increased; Respiratory Failure; White Blood Cell Count Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Furosemide			C				Not Reported
	Lisinopril			C				Not Reported
	Metoprolol			C				Not Reported
	Norepinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Morphine			C				Not Reported
	Propofol			C				Not Reported
	Enoxaparin			C				Not Reported
	Aspirin			C				Not Reported
	Docusate			C				Not Reported
	Pantoprazole			C				Not Reported
	Mehtylprednisolone			C				Not Reported

		Insulin Glargine			C					Not Reported
		Venlafaxine			C					Not Reported
		Duoneb			C					Not Reported
		Guaifenesin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874708	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Allopurinol			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874713	DIRECT	Y	OT			25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874717	DIRECT	Y				39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Orthostatic Hypotension	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amlodipine			C				Not Reported

			Ascorbic Acid			C					Not Reported
			Carvedilol			C					Not Reported
			Enoxaparin			C					Not Reported
			Levothyroxine			C					Not Reported
			Pantoprazole			C					Not Reported
			Zinc Sulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874751	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17874927	DIRECT	Y				63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17875016	DIRECT	Y	OT			91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Renal Impairment	Remdesivir			S				Gilead
	Amiodarone			C				Not Reported
	Apixaban			C				Not Reported
	Covalescent Plasma			C				Not Reported
	Bumex			C				Not Reported
	Plavix			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Protonix			C				Not Reported
	Metoprolol			C				Not Reported

		Nitroglycerin Patch			C					Not Reported
		Hydralazine			C					Not Reported
		Isosorbide Mononitrate			C					Not Reported
		Tamsulosin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17875022	DIRECT	Y				59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17875057	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Procalcitonin Increased; Respiratory Distress; Troponin Increased; White Blood Cell Count Increased	Remdesivir			S				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Atracurium			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Dobutamine			C				Not Reported
	Enoxaparin			C				Not Reported
	Epoprostenol			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Phenylephrine			C				Not Reported
	Heparin			C				Not Reported
	Vitamin C			C				Not Reported
	Hydrocortisone			C				Not Reported
	Thiamine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17875136	DIRECT	Y	RI			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported
	Methylprednisolone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17800831	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0467444		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17863292	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470078		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Dysphagia; End Stage Renal Disease; Failure To Thrive; Pneumonia Viral; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Zosyn			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875072	DIRECT	Y				47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Issue	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875074	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Ascorbic Acid 500mg			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Atorvastatin 20 Mg			C				Not Reported
	Duoneb			C				Not Reported
	Lovenox			C				Not Reported
	Zosyn			C				Not Reported
	Vancomycin Iv			C				Not Reported
	Acetaminophen 650mg Prn			C				Not Reported
	Precedex			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl Iv Drip			C				Not Reported
	Doxycycline			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875122	DIRECT	Y	DE			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardio-Respiratory Arrest; Hypoxia; Ventricular Tachycardia	Remdesivir	Y		S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875235	DIRECT	Y	DE, OT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardio-Respiratory Arrest; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Lorazepam			C				Not Reported
	D5w With 3 Amps Bicarb			C				Not Reported
	Epoprostenol			C				Not Reported
	Heparin			C				Not Reported
	Ketamine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Convalescent Serum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875456	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Blood Magnesium Increased; Condition Aggravated	Remdesivir			S				Not Reported
	Resmedivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875590	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ampicillin/Sulbactam			C				Not Reported

	Apixaban			C					Not Reported
	Chlorpromazine			C					Not Reported
	Diltiazem			C					Not Reported
	Glycopyrrolate			C					Not Reported
	Levothyroxine			C					Not Reported
	Melatonin			C					Not Reported
	Dulera			C					Not Reported
	Pantoprazole			C					Not Reported
	Prednisone			C					Not Reported
	Sertraline			C					Not Reported
	Hydromorphone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875594	DIRECT	Y	HO			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Ascorbic Acid 500 Mg			C				Not Reported
	Candesartan 16 Mg			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Lantus 5 Units			C				Not Reported
	Methylprednisolone 50 Mg			C				Not Reported
	Metoprolol Succinate 25 Mg			C				Not Reported
	Nifidipine 30 Mg			C				Not Reported
	Pravastatin 20 Mg			C				Not Reported
	Zinc Sulfate 220 Mg			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Dexmedotomidine Infusion			C				Not Reported
	Epinephrine Infusion			C				Not Reported
	Heparin Infusion			C				Not Reported
	Vasopressin Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875600	DIRECT	Y				88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Transaminases Increased;	Remdesivir			S	Intravenous bolus			Gilead
	Albuterol			C				Not Reported

Urinary Bladder Haemorrhage; Urinary Retention	Atorvastatin			C					Not Reported
	Enoxaparin			C					Not Reported
	Levofloxacin			C					Not Reported
	Methylprednisolone			C					Not Reported
	Pantoprazole			C					Not Reported
	Senna			C					Not Reported
	Warfarin			C					Not Reported
	Acetaminophen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875647	DIRECT	Y	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Gilead
	Propofol			C				Not Reported
	Hydromorphone			C				Not Reported
	Norepinephrine			C				Not Reported
	Docusate-Senna			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875801	DIRECT	Y	DE			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cardiac Arrest; Hypotension; Hypoxia; Lung Infiltration; Paralysis; Procalcitonin Increased; Renal Failure	Remdesivir Eua			S				Not Reported
	Vancomycin			C				Not Reported
	Tocilizumab			C				Not Reported
	Pentoxifylline			C				Not Reported
	Rocuronium			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Metoprolol			C				Not Reported
	Kaletra			C				Not Reported
	Heparin			C				Not Reported
	Cisatricurium			C				Not Reported
	Cefepime			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875863	DIRECT	Y	LT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Cardio-Respiratory Arrest; Pulse Absent	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Heparin			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Regular			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported
	Clonazepam			C				Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17875891	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous drip			Gilead
	Acyclovir			C				Not Reported
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Vitamin D3			C				Not Reported
	Clonidine			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Guaifenesin			C				Not Reported
	Midodrine			C				Not Reported
	Multivitamin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Potassium Phosphate			C				Not Reported
	Sodium Chloride Inhaled			C				Not Reported
	Sodium Phosphate			C				Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported
	Thiamine			C				Not Reported
	Oxycodone			C				Not Reported

	Fentanyl			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876085	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Urgency; Renal Impairment	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminiphen			C				Not Reported
	Amlodipine			C				Not Reported
	Aspirin			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Labetalol Prn			C				Not Reported
	Lactulose			C				Not Reported
	Quetiapine			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Ketamine Drip			C				Not Reported
	Midazolam Drip			C				Not Reported
	Propofol Drip			C				Not Reported
	Rocuronium Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876090	DIRECT	Y	DE			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Cardiac Arrest; Confusional State; Hypoxia; Obstructive Airways Disorder; Pneumothorax; Pulse Absent; Rales; Swelling	Remdesivir			S	Intravenous bolus			Gilead
	Thiamine			C				Not Reported
	Seroquel			C				Not Reported
	Haloperidol			C				Not Reported
	Pantoprazole			C				Not Reported
	Methylprednisolone			C				Not Reported
	Ketorolac			C				Not Reported
	Hydrocortisone			C				Not Reported
	Heparin			C				Not Reported
	Enoxaparin			C				Not Reported
	Cefepime			C				Not Reported

	Ascorbic Acid				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876168	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876171	DIRECT	Y	OT			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876176	DIRECT	Y	DE			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid			C				Not Reported
	Bumetanide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Escitalopram			C				Not Reported
	Famotidine			C				Not Reported
	Hydrocortisone			C				Not Reported
	Insulin			C				Not Reported
	Levothryoxine			C				Not Reported

		Lorazepam			C					Not Reported
		Magnesium Sulfate			C					Not Reported
		Piperacillin-Tazobactam			C					Not Reported
		Rocuronium			C					Not Reported
		Vancomycin			C					Not Reported
		Fentanyl			C					Not Reported
		Midazolam			C					Not Reported
		Dexmedetomidine			C					Not Reported
		Heparin			C					Not Reported
		Norepinephrine			C					Not Reported
		Convalenscent Serum			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876180	DIRECT	Y	HO			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Remdesivir	Y		S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876191	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Hycodan			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876212	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once (Loading Dose;		Gilead
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported

	Fentanyl	C		Not Reported
	Hydralazine	C		Not Reported
	Insulin Aspart	C		Not Reported
	Insulin Glargine	C		Not Reported
	Lisinopril	C		Not Reported
	Metformin	C		Not Reported
	Midazolam	C		Not Reported
	0.9%Ns	C		Not Reported
	Norepinephrine	C		Not Reported
	Pantoprazole	C		Not Reported
	Piperacillin/Tazobactam	C		Not Reported
	Propofol	C		Not Reported
	Rocuronium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876217	DIRECT	Y				47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip		3 DAY	Gilead
	Acetaminophen			C				Not Reported
	Albuterol Hfa Inhaler			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876300	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Monitoring Procedure Incorrectly Performed; Incorrect Dose Administered; Product Dispensing Error; Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876302	DIRECT	Y	OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Empty Sella Syndrome	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin			C				Not Reported
	Metformin			C				Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17876309	DIRECT	Y	OT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:5 Day Treatment;	5 DAY	Gilead
	Atorvastatin 10mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17877925	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470627		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17877930	EXPEDITED (15-DAY)		DE	US-GILEAD-2020-0470607		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fluid Overload; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not	100 Mg, Qd		Gilead

					otherwise specified)				
	Convalescent Plasma			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17879118	DIRECT	Y	OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Blood Magnesium Increased; Condition Aggravated	Remdesivir			S				Not Reported
	Resmedivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17879136	DIRECT	Y	HO			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Creatinine Renal Clearance Decreased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 HR	Gilead
	Metronidazole			C				Not Reported
	Vancomycin			C				Not Reported
	Cefepime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17879147	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Bilirubin Increased; Blood Lactate Dehydrogenase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Tocilizumab			C				Not Reported
	Doxycycline			C				Not Reported
	Rocephin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17879156	DIRECT	Y	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Hallucination; Hallucination, Auditory; Suicidal Ideation	Remdesivir			S	Intravenous drip			Gilead
	Benzonatate (Tessalon Perles			C				Not Reported
	Dextromethorphan			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Acetaminophen			C				Not Reported
	Chlorhexidine Oral			C				Not Reported
	Enoxaparin			C				Not Reported
	Labetolol			C				Not Reported
	Guaifensin Ac			C				Not Reported
	Nifedipine			C				Not Reported
	Norco 5-325			C				Not Reported
	Heparin Porcine			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17879174	DIRECT	Y	DE			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity; Nephropathy Toxic	Remdesivir	Y		S	Intravenous bolus	Other Frequency:X 1;		Gilead
	Aspirin 81mg			C				Not Reported
	Atorvastatin 40mg			C				Not Reported
	Cefepime 2g			C				Not Reported
	Chlorhexidine Mouthwash			C				Not Reported
	Clopidigrel 75mg			C				Not Reported
	Dexamethasone 20mg			C				Not Reported
	Enoxiparin 40mg			C				Not Reported
	Famotidine 20mg			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Regular			C				Not Reported
	Levofloxacin 750mg			C				Not Reported
	Methylprednisolone 40mg			C				Not Reported
	Vancomycin			C				Not Reported
	Aceaminophen 650mg			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Heparin Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported

		Phenylephrine Drip			C						Not Reported
		Propofol Drip			C						Not Reported
		Midazolam Drip			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17879183	DIRECT	Y	LT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Cessation	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2020	17879308	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17818539	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468282		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Oxcarbazepine			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Levetiracetam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17818552	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0468312		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypoxia; Respiratory Failure; Shock	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Convalescent Plasma			C		Unk		Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Phenylephrine			C				Not Reported
	Potassium Phosphate Dibasic			C				Not Reported
	Potassium Chloride			C				Not Reported
	Prismasate Bk0/3.5			C				Not Reported
	Prismasol			C				Not Reported
	Propofol			C				Not Reported
	Scopolamine Aminoxide			C				Not Reported
	Sodium Chloride			C				Not Reported
	Vancomycin			C		Unk		Not Reported
	Vasopressin			C				Not Reported
	Vitamin B12 Aaa			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Normosol			C				Not Reported
	Enoxaparin			C				Not Reported
	Epinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Iopamidol			C				Not Reported
	Lactated Ringers			C				Not Reported
	Lorazepam			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Melatonin			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Morphine			C				Not Reported

	Norepinephrine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880273	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Flushing; Infusion Related Reaction	Remdesivir Injection 100 Mg/20 Ml Solution	Y		S	Intravenous drip			Gilead
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Cefepim 2gm			C				Not Reported
	Cholecalciferol 1000 Iu			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Famotidine 20 Mg			C				Not Reported
	Ferrous Sulfate 300 Mg			C				Not Reported
	Levothyroxine 75 Mcg			C				Not Reported
	Midodrine 5 Mg			C				Not Reported
	Prednisone 5 Mg			C				Not Reported
	Vancomycin 1gm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880274	DIRECT	Y				36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)		7 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880275	DIRECT	Y	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Remdesivir	Y		S	Intravenous bolus			Gilead
	Furosemide			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880279	DIRECT	Y				68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Levofloxacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880282	DIRECT	Y				93 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Hypovolaemia; Infusion Related Reaction	Remdesivir			S				Not Reported
	Ancef 4.5g			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880286	DIRECT	Y	HO			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880769	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous drip			Gilead
	Bumex			C				Not Reported
	Famotidine			C				Not Reported
	Insulin			C				Not Reported
	Heparin			C				Not Reported

		Midodrine			C					Not Reported
		Zosyn			C					Not Reported
		Prednisone			C					Not Reported
		Vancomycin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880876	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17880882	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoxia; Renal Impairment	Remdesivir			S	Intravenous drip			Gilead
	Vancomycin Iv			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Fluconazole			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Zinc			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Vit D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881236	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Kink; Product Dose Omission Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

			Furosemide			C					Not Reported
			Heparin			C					Not Reported
			Lactobacillus Rhamnosus			C					Not Reported
			Methylprednisolone Sodium Succinate			C					Not Reported
			Potassium Chloride			C					Not Reported
			Lr Infusion			C					Not Reported
			Ns Bolus			C					Not Reported
			Melatonin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881241	DIRECT	Y	OT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Desmpressin			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Hydrocortisone Iv			C				Not Reported
	Levothyroxine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Acetaminophen			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881248	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881252	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881257	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Impairment; Renal Tubular Injury	Remdesivir			S			3 DAY	Gilead
	Lisinopril			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Famotidine			C				Not Reported
	Hydralazine			C				Not Reported
	Hydrocortisone Sod Succinate			C				Not Reported
	Nicardipine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Simvastatin			C				Not Reported
	Sodium Chloride Infusion			C				Not Reported
	Sodium Phosphate In D5w			C				Not Reported
	Potassium Phosphate			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Glargine			C				Not Reported
	Fentanyl			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881264	DIRECT	Y	DE, DS, LT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Ischaemic Stroke; Nervous System Disorder	Remdesivir Injection	Y		S	Intravenous (not otherwise specified)			Gilead
	Covid-19 Convalescent Plasma			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Amiodarone Drip			C				Not Reported
	Vancomcycin			C				Not Reported

		Zosyn			C					Not Reported
		Azithromycin			C					Not Reported
		Prophylactic Lovenox (40 Mg Sq Bid)			C					Not Reported
		Therapeutic Lovenox (80 Mg Sq Bid)			C					Not Reported
		Prophylactic Lovenox (40 Mg Sq Bid)			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881269	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Methylprednisolone			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881367	EXPEDITED (15-DAY)			US-GILEAD-2020-0469487		16 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Storage Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17881967	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470949		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome;	Remdesivir			S	Unknown			Gilead

Shock

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882192	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0471151		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Death; Oxygen Consumption Increased; Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydralazine			C		Unk		Not Reported
	Imdur			C		Unk		Not Reported
	Ketorolac			C		Unk		Not Reported
	Levemir			C		Unk		Not Reported
	Linezolid			C		Unk		Not Reported
	Memantine			C		Unk		Not Reported
	Novolog			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Potassium Phosphate Dibasic; Sodium Phosphate			C		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]			C		Unk		Not Reported
	Primidone			C		Unk		Not Reported
	Pyridoxine			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Vitamin D [Colecalciferol]			C		Unk		Not Reported
	Convalescent Plasma			C		Unk		Not Reported
	Combinent Respimat			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Anastrozole			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported

	Azithromycin	C	Unk	Not Reported
	Coreg	C	Unk	Not Reported
	Cefepime	C	Unk	Not Reported
	Clopidogrel	C	Unk	Not Reported
	Cyanocobalamin	C	Unk	Not Reported
	Donepezil	C	Unk	Not Reported
	Famotidine	C	Unk	Not Reported
	Ferrous Sulfate	C	Unk	Not Reported
	Folic Acid	C	Unk	Not Reported
	Gabapentin	C	Unk	Not Reported
	Insulin	C	Unk	Not Reported
	Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported
	Nitroglycerin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882290	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0470081		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin-Mip [Vancomycin]			C				Not Reported
	Enoxaparin			C				Not Reported
	Thiamine			C				Not Reported
	Zinc			C				Not Reported
	Bumetanide			C				Not Reported
	Clonazepam			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Dobutamine			C				Not Reported

	Fentanyl			C						Not Reported
	Methylprednisolone			C						Not Reported
	Acetaminophen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882668	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470292		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882688	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469668		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882689	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469669		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882771	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469821		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Remdesivir			S	Intravenous (not otherwise specified)	200mg X1, 100mg X 1		Gilead
Supraventricular; Atrial Fibrillation; Atrial Flutter; Ejection Fraction; Heart	Remdesivir			S	Intravenous (not	100 Mg, Daily X3		Gilead

Rate Increased; Hypotension; Ischaemia				otherwise specified)		
	Levofloxacin		S	Unknown		Not Reported
	Levothyroxine		S	Unknown		Not Reported
	Metronidazole		C			Not Reported
	Amiodarone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17882790	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0469839		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Topamax			C				Not Reported
	Namenda			C				Not Reported
	Imdur			C				Not Reported
	Neurontin			C				Not Reported
	Breo Ellipta			C				Not Reported
	Pepcid Ac			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Cardizem Cd			C				Not Reported
	Levetiracetam			C				Not Reported
	Combivent			C				Not Reported
	Heparin			C				Not Reported
	Dextrose			C				Not Reported
	Morphine			C				Not Reported
	Rocephin Biochemie			C				Not Reported
	Zithromax			C				Not Reported
	Nystatin			C				Not Reported
	Cardizem Cd			C				Not Reported
	Tylenol			C				Not Reported
	Eliquis			C				Not Reported
	Sodium Chloride			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Potassium Chloride			C				Not Reported
	Decadron [Dexamethasone]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17883629	DIRECT	Y	OT			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Myocarditis; Respiratory Failure; Transaminases Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17883633	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17883639	DIRECT	Y				71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17883645	DIRECT	Y	HO			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hypotension	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead

	Vancomycin			C						Not Reported
	Tenofovir			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	17883718	DIRECT	Y				59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Condition Aggravated	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17837784	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468230		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Inappropriate Schedule Of Product Administration; Product Use Issue	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884813	DIRECT	Y	DE			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Glomerular Filtration Rate Decreased; Tachycardia; Tachypnoea	Remdesivir Under Emergency Use Authorization (Eua			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884818	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypotension	Remdesivir	Y	S	Intravenous (not otherwise specified)	5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884825	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonotate			C				Not Reported
	Bisacodyl			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported
	Guafenesin			C				Not Reported
	Hydrocodone Acetaminophen			C				Not Reported
	Morphine			C				Not Reported
	Orphenadrine			C				Not Reported
	Prednisone			C				Not Reported
	Docusate Sennosides			C				Not Reported
	Sodium Chloride 0.9%			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884829	DIRECT	Y	DE			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:1100 Mg Total;		Gilead
	Albumin Human 5%			C				Not Reported
	Allopurinol			C				Not Reported
	Apixaban			C				Not Reported
	Atorvastatin			C				Not Reported
	Coreg			C				Not Reported

			Enoxaparin			C				Not Reported
			Duloxetine			C				Not Reported
			Ertapenem			C				Not Reported
			Fentanyl			C				Not Reported
			Folic Acid			C				Not Reported
			Furosemide			C				Not Reported
			Hydroxychloroquine			C				Not Reported
			Insulin			C				Not Reported
			Methylprednisolone			C				Not Reported
			Pantoprazole			C				Not Reported
			Phenylephrine			C				Not Reported
			Pregabalin			C				Not Reported
			Propofol			C				Not Reported
			Sulfasalazine			C				Not Reported
			Vitamin D			C				Not Reported
			Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884835	DIRECT	Y	OT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Zosyn			S	Intravenous (not otherwise specified)			Unknown
	Zosyn			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884836	DIRECT	Y				58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir Under Emergency Use Authorization (Eua			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884843	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Dyspnoea; Nausea; Oxygen Saturation Decreased; Pain; Vision Blurred; Vomiting	Remdesivir 100 Mg Vials	Y		S	Intravenous bolus			Gilead
	Doxycycline 100 Mg Po Bid			C				Not Reported
	Methylprednisolone 40 Mg Iv Bid			C				Not Reported
	Furosemide 40mg Iv Bid			C				Not Reported
	Hydroxyzine 25 Mg Poq6h Prn			C				Not Reported
	Venlafaxine 37.5mg Po Daily			C				Not Reported
	Enoxaparin 50 Mg Sq Q12h			C				Not Reported
	Trazodone 50 Mg Po Qpm			C				Not Reported
	Melatonin 9 Mg Po Qpm			C				Not Reported
	Folic Acid 1mg Po Daily			C				Not Reported
	Pantoprazole 40mg Bid			C				Not Reported
	Thiamine 100 Mg Iv Daily			C				Not Reported
	Albuterol 2 Puffs Qid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884920	DIRECT	Y	OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydromorphone			C				Not Reported
	Prochloroperazine			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884929	DIRECT	Y	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test	Remdesivir			S	Intravenous drip			Not Reported

Increased	Acetaminophen	C	Not Reported
	Albuterol	C	Not Reported
	Symbicort	C	Not Reported
	Enoxaparin	C	Not Reported
	Lamotrigine	C	Not Reported
	Melatonin	C	Not Reported
	Tramadol	C	Not Reported
	Trazodone	C	Not Reported
	Venlafaxine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884965	DIRECT	Y	DE			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Oxygen Saturation Decreased	Remdesivir Under Emergency Use Authorization (Eua			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884971	DIRECT	Y	OT			9 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous drip		3 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884976	DIRECT	Y				63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Presyncope; Syncope; Therapy Cessation	Remdesivir Under Emergency Use Authorization (Eua			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884982	DIRECT	Y				79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Haemodialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Piperacillin-Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884990	DIRECT	Y	HO			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Tocilizumab 400 Mg Iv X1			C				Not Reported
	Hydroxychloroquine 200 Mg Po Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17884998	DIRECT	Y				76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:One Time;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885006	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Azotaemia; Fluid Overload; Inflammation	Remdesivir Iv Solution	Y		S	Intravenous bolus			Gilead
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Enoxaparin			C				Not Reported

	Lispro			C					Not Reported
	Hydromorphone			C					Not Reported
	Norepinephrine			C					Not Reported
	Propofol			C					Not Reported
	Acetaminophen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885013	DIRECT	Y	OT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead
	Ascorbic Acid 150mg Oral			C				Not Reported
	Enoxaparin 100mg Sc			C				Not Reported
	Zitrhromax 500mg Iv			C				Not Reported
	Famotidine 20mg Iv Daily			C				Not Reported
	Lidocaine 5% Patch			C				Not Reported
	Methylprednisolone 125mg Iv Q8h			C				Not Reported
	Thiamine 100mg Iv Daily			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported
	Acetaminophen 650mg Oral Q6h Prn			C				Not Reported
	Cycylcobenzaprine 10mg Oral Tid Prn			C				Not Reported
	Morphine 1mg Iv Q8h Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17885020	DIRECT	Y	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17886243	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470876		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fluconazole			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Insulin Regular Hm			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Sodium Phosphate			C		Unk		Not Reported
	Succinylcholine [Suxamethonium Chloride]			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17887527	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470376		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Musculoskeletal Stiffness	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Gabapentin			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Pantoprazole			C				Not Reported
	Rivaroxaban			C				Not Reported
	Ropinirole			C				Not Reported
	Tamsulosin			C				Not Reported
	Aspirin (E.C.)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17887565	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0470402		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Amlodipine			C				Not Reported
	Dextromethorphan			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Heparin			C				Not Reported
	Lactated Ringers			C				Not Reported
	Sodium Chloride & Dextrose			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17887576	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470407		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea;	Remdesivir			S	Intravenous (not	Unk, Qd		Gilead

Hypertension; Malaise

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17887628	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470406		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17887630	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470688		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Unasyn [Ampicillin Sodium; Sulbactam Sodium]			C				Not Reported
	Furosemide			C				Not Reported
	Keppra			C				Not Reported
	Fentanyl			C				Not Reported
	Versed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17887633	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0470433		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17887638	EXPEDITED (15-DAY)			US-GILEAD-2020-0469605		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Insulin Regular Beef			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888175	DIRECT	Y	DE			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bilevel Positive Airway Pressure; Dysphagia; Palliative Care; Respiratory Failure	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888194	DIRECT	Y				80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amiodarone			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888195	DIRECT					52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888199	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Depression; Fear; Hypotension; Lacrimation Increased	Remdesivir			S	Intravenous drip			Gilead
	Diltiazem			C				Not Reported
	Metoprolol			C				Not Reported
	Cetirizine			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Detemir			C				Not Reported
	Metformin			C				Not Reported
	Novolog			C				Not Reported
	Ropinirole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888200	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Pneumonia; Pneumonia Pseudomonal	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Precedex			C				Not Reported
	Meropenem			C				Not Reported
	Micafungin			C				Not Reported
	Azithromycin			C				Not Reported
	Vasopressin			C				Not Reported
	Metronidazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888215	DIRECT	Y				44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Renal Function Test Abnormal	Remdesivir			S	Intravenous (not otherwise specified)		6 DAY	Gilead
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888220	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Pressure Decreased; Dyspnoea; Gastrointestinal Haemorrhage; Haematocrit Decreased; Haemoglobin Decreased; Hyperkalaemia; Oxygen Saturation Decreased; Thrombocytopenia	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Convalenscent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888224	DIRECT	Y	OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Renal Tubular Necrosis	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888229	DIRECT	Y				56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Systolic Increased; Chest Discomfort; Nausea	Remdesivir	Y		S	Intravenous drip			Gilead
	Acetaminophen 650 Mg Tablet			C				Not Reported
	Lidocaine 4% Transdermal Patch			C				Not Reported
	Enoxaparin 30 Mg Subcutanous Injection			C				Not Reported
	Docusate 100 Mg Capsule			C				Not Reported
	Polyethylene Glycol 17g Powder			C				Not Reported
	Senna Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888251	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Dialysis; Pneumonia; Respiratory Failure; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen Prn			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Ascorbic Acid (Intravenous)			C				Not Reported
	Azithromycin (Intravenous)			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin/Dextromethorphan Prn (Got 1 Dose)			C				Not Reported
	Hydrocodone/Acetaminophen Tablets Prn (Got 1 Dose)			C				Not Reported
	Orphenadrine Er Tablets Prn (Got 1 Dose)			C				Not Reported
	Zinc Sulfate Capsules			C				Not Reported
	Cisatracurium			C				Not Reported
	Fentanyl Intravenous Drip			C				Not Reported
	Lubricant Eye Ointment			C				Not Reported
	Lorazepam Prn			C				Not Reported
	Norepinephrine Intravenous Drip			C				Not Reported
	Propofol Intravenous Drip			C				Not Reported

		Succinylcholine (1 Dose)			C					Not Reported
		Natural Tears Drops			C					Not Reported
		Veruronium Prn (Got 1 Dose On 6/5)			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888256	DIRECT	Y	DS, LT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888259	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888263	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin 40 Mg			C				Not Reported
	Fluoxetine 20 Mg			C				Not Reported
	Propofol Infusion			C				Not Reported
	Fentanyl Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888265	DIRECT	Y	HO			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y	S	Intravenous bolus	Other Frequency:One Time;	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888269	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY	Gilead
	Amiodarone Iv			C				Not Reported
	Apixaban			C				Not Reported
	Diltiazem Iv			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Tocilizumab			C				Not Reported
	Heparin Iv			C				Not Reported
	Adenosine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888273	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Disseminated Intravascular Coagulation; Shock	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Succinylcholine			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Cisatracurium			C				Not Reported
	Propofol			C				Not Reported
	Ketamine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported

Heparin	C		Not Reported
Insulin Lispro	C		Not Reported
Pericolace	C		Not Reported
Vancomycin	C		Not Reported
Insulin Regular Human	C		Not Reported
Midazolam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888277	DIRECT	Y	DE			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration	Remdesivir Treatment Under Emergency Use Authorization (Eua)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2020	17888314	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17873144	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470616		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Epistaxis; Hypotension; Pulseless Electrical Activity; Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Rivaroxaban			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889442	DIRECT	Y	DE			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889551	DIRECT	Y	HO			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once - Loading Dos;		Gilead
	Actemra	Y		S				Genentech
	Zosyn			C				Not Reported
	Vancomycin			C				Not Reported
	Thiamine			C				Not Reported
	Hydrocortisone			C				Not Reported
	Synthroid			C				Not Reported
	Versed			C				Not Reported
	Pepcid			C				Not Reported
	Insulin			C				Not Reported
	Aspirin			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Albumin			C				Not Reported
	Heparin			C				Not Reported
	Fentanyl			C				Not Reported
	Amiodarone			C				Not Reported
	Epinephrine			C				Not Reported
	Milrinone			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889554	DIRECT	Y	DE			91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; General Physical Health Deterioration	Remdesivir			S				Gilead
	Dexamethasone 20 Mg Lv Daily			C				Not Reported
	Insulin			C				Not Reported
	Lorazepam 0.5 Mg Le1			C				Not Reported
	Metoprolol 2.5 Mg Lv X1			C				Not Reported
	Metoprolol 2.5 Mg Q6h Iv			C				Not Reported
	Nitroglycerin 0.4 Mg/Hr Patch Daily			C				Not Reported
	Protonix 40 Mg Lv Q12h			C				Not Reported
	Hydromorphone			C				Not Reported
	Bicarb 8.4% Continuous Infusion			C				Not Reported
	Morphine 1 Mg Lv Q4h Pn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889580	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Kidney Injury; Ischaemic Hepatitis	Remdesivir			S				Gilead
	Selinexor Vs. Placebo			C				Not Reported
	Acetaminophen			C				Not Reported
	Furosemide			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889585	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Dyspnoea; Ear Pruritus; Eye Irritation; Eye Pruritus; Throat Irritation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Apixaban			C				Not Reported
	Montelukast			C				Not Reported
	Guaifenesin			C				Not Reported
	Pantoprazole			C				Not Reported
	Fluticasone-Vilanterol			C				Not Reported
	Acetaminophen			C				Not Reported
	Insulin Lispro			C				Not Reported

Melatonin	C		Not Reported
Zinc Sulfate	C		Not Reported
Vitamin C	C		Not Reported
Vitamin D	C		Not Reported
Albuterol-Ipratropium	C		Not Reported
Insulin Glargine	C		Not Reported
Methylprednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889591	DIRECT	Y				45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889595	DIRECT	Y				68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889600	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Dose Omission Issue	Remdesivir			S	Intravenous (not otherwise specified)		10 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17889785	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Chills; Dyspnoea; Hypertension; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip		1 HR	Gilead
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892601	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0471143		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endotracheal Intubation; Liver Function Test Increased; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Bupropion			C				Not Reported
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Benzocaine-Menthol			C				Not Reported
	Bisacodyl			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enoxaparin [Enoxaparin Sodium]			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Guaifenesin			C				Not Reported
	Hydromorphone			C				Not Reported
	Melatonin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Nystatin			C				Not Reported
	Ondansetron			C				Not Reported
	Polyethylene Glycol [Macrogol]			C				Not Reported
	Potassium Bicarbonate/Citric Acid			C				Not Reported
	Propofol			C				Not Reported

	Senna [Senna Alexandrina]	C		Not Reported
	Sertraline	C		Not Reported
	Temazepam	C		Not Reported
	Trazodone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892603	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470917		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Endotracheal Intubation; Heart Rate Decreased; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Propofol			C	Intravenous (not otherwise specified)	50-75mcg/Kg/Min		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892604	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470948		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Acetaminophen			C				Not Reported
	Acetylcysteine			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	D50w			C				Not Reported
	Enoxaparin			C				Not Reported
	Etomidate			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Lispro			C				Not Reported
	Ipratropium			C				Not Reported
	Methylprednisolone			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported

	Sodium Chloride			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892626	EXPEDITED (15-DAY)			US-GILEAD-2020-0470372		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Enoxaparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Povidone Iodine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Simvastatin			C				Not Reported
	Insulin Lispro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17892627	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470082		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Decreased	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894663	DIRECT	Y				25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Erythema; Infusion Site Extravasation; Infusion Site Warmth	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894689	DIRECT	Y				63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894693	DIRECT	Y	OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894698	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894703	DIRECT	Y	OT			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Rhabdomyolysis	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894725	DIRECT	Y	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir			S				Unknown

Increased; Liver Function Test Increased; Therapy Cessation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894728	DIRECT		OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity; Hypotension; Platelet Count Decreased; Pneumonia; Renal Impairment; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Acetylcysteine Inhalation And Po			C				Not Reported
	Ascorbic Acid (Intravenous)			C				Not Reported
	Aspirin Suppository X 1 Dose			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levalbutorol Inhalation			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Pantoprazole (Intravenous)			C				Not Reported
	Propofol Drip			C				Not Reported
	Normal Saline Drip			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Zosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894732	DIRECT	Y	DE			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypoxia; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894735	DIRECT	Y				6 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Packaging Confusion; Wrong Product Administered; Wrong Technique In Product Usage Process	Remdesivir	S	Intravenous drip	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894738	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Artery Aneurysm; Retroperitoneal Haemorrhage	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin Ec 81 Mg			C				Not Reported
	Azithromycin 250 Mg			C				Not Reported
	Carvedilol 3.125 Mg			C				Not Reported
	Cefepime 2 G			C				Not Reported
	Cotrimoxazole 400-80			C				Not Reported
	Famotidine 40 Mg			C				Not Reported
	Heparin 5000 Units			C				Not Reported
	Isavuconazole 372 Mg			C				Not Reported
	Prednisone 10 Mg			C				Not Reported
	Tacrolimus 1 Mg			C				Not Reported
	Valganciclovir 450 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894743	DIRECT	Y	OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Lactic Acidosis	Remdesivir			S				Gilead
	Convalescent Covid Plasma			C				Not Reported
	Tocilizumab			C				Not Reported
	Vancomycin			C				Not Reported
	Ceftazidime			C				Not Reported
	Epinephrine			C				Not Reported
	Dopamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894748	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894783	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Tocilizumab			S	Intravenous drip		1 HR	Genentech
	Atorvastatin 20 Mg			C				Not Reported
	Heparin 7500 Units			C				Not Reported
	Culturelle 1 Capsule			C				Not Reported
	Losartan 25 Mg			C				Not Reported
	Cefepime 2 G Iv			C				Not Reported
	Vancomycin			C				Not Reported
	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17894789	DIRECT	Y	OT			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17895655	DIRECT	Y	LT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hypotension; Melaena	Enoxaparin (Enoxaparin 40mg/0.4ml Inj)			S	Subcutaneous			Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17895735	DIRECT	Y	RI			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Erythema Multiforme; Extravasation; Peripheral Swelling; Swelling	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Frequency:Am;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17895854	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17896169	DIRECT	Y	HO, RI			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Respiratory Failure	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17896172	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Hepatic Enzyme Increased;	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

Rhabdomyolysis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2020	17896431	DIRECT	Y	RI			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Haemodialysis; Hypotension; Nephropathy Toxic; Renal Impairment; Urate Nephropathy	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17894751	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip	Other Frequency:Load;		Gilead
	Guaifenesin/Dxm			C				Not Reported
	Apap 650mg			C				Not Reported
	Enoxaparin 40mg Bid			C				Not Reported
	Lactobacillus			C				Not Reported
	Levofloxacin 750mg Iv			C				Not Reported
	Kbicarb/Kcitrate			C				Not Reported
	Ns			C				Not Reported
	Cefepime 1g			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2020	17894755	DIRECT	Y				34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17894759	DIRECT	Y				54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Rash Papular	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17894773	DIRECT	Y				77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:200mg Then 100mg;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17894794	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Infusion Site Swelling	Remdesivir			S	Intravenous drip			Gilead
	Vitamin D3 5000 Units			C				Not Reported
	Ceftriaxone 1 Gm			C				Not Reported
	Thiamine 100mg			C				Not Reported
	Azithromycin 500mg			C				Not Reported
	Enoxaparin 40mg			C				Not Reported
	Acetaminophen 650 Mg			C				Not Reported
	Atorvastatin 500mg			C				Not Reported
	Zinc Sulfate 220			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2020	17896437	DIRECT	Y	DE			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Treatment Failure	Remdesivir Solution 100 Mg Vial	Y		S	Intravenous (not			Gilead

			otherwise specified)	
	Remdesivir Solution 100 Mg Vial Y	S	Intravenous (not otherwise specified)	Gilead
	Carboxymethylcellulose	C		Not Reported
	Chlorhexidine	C		Not Reported
	Enoxaparin	C		Not Reported
	Fluconazole	C		Not Reported
	Furosemide	C		Not Reported
	Lipid (Smoflipid)	C		Not Reported
	Meropenem	C		Not Reported
	Methylprednisolone Sodium Succinate	C		Not Reported
	Mupirocin	C		Not Reported
	Pantoprazole	C		Not Reported
	Vancomycin	C		Not Reported
	White Petrolatum-Mineral Oil Eye Ointment	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17818858	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0468531		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Erythema; Rash Macular; Rash Vesicular	Remdesivir			S	Unknown	Unk Mg		Gilead
	Remdesivir			S	Unknown	Unk Mg		Gilead
	Acetaminophen			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17848044	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469503		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cardiac Arrest; Glomerular Filtration Rate Decreased; Liver Function Test Increased; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Norco			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Amiodarone			C				Not Reported
	Amlodipine			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Atorvastatin			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine Gluconate			C				Not Reported
	Cholecalciferol			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Digoxin			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Heparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Losartan			C				Not Reported
	Meropenem			C				Not Reported
	Metformin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Metoprolol			C				Not Reported
	Midazolam			C				Not Reported
	Nitroglycerin			C				Not Reported
	Norepinephrine			C				Not Reported

			Nortriptyline			C					Not Reported
			Phenylephrine			C					Not Reported
			Propofol			C					Not Reported
			Tocilizumab			C					Not Reported
			Warfarin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17896456	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoeic Attack; Areflexia; Cardiac Arrest; Electrocardiogram St Segment Elevation; Hypotension; Pulse Absent; Pulseless Electrical Activity; Sinus Tachycardia; Tachycardia	Remdesivir Solution 100 Mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Solution 100 Mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol Mdi			C				Not Reported
	Albuterol Neb Soln			C				Not Reported
	Aspirin Ec			C				Not Reported
	Chlorhexidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Fluticasone Furoate-Vilanterol			C				Not Reported
	Furosemide			C				Not Reported
	Glycopyrrolate			C				Not Reported
	Insulin Aspart			C				Not Reported
	Lidocaine			C				Not Reported
	Mupirocin			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Senna-Docusate			C				Not Reported
	Tamsulosin			C				Not Reported
	Tiotropium			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17896637	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0471302		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Unknown	100 Mg		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17896769	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0471271		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Body Temperature Increased; Leukocytosis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Pantoprazole			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Pantoprazole			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Lactated Ringers			C		Unk		Not Reported
	Humalog			C		Unk		Not Reported
	Plasma			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen			C		650 Mg		Not Reported
	Ibuprofen			C				Not Reported
	Diphenhydramine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17898685	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469453		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		90 Mcg		Not Reported
	Ascorbic Acid			C		500 Mg		Not Reported

Benzonatate	C	100 Mg	Not Reported
Dexamethasone	C	20 Mg	Not Reported
Guaifenesin And Dextromethorphan	C	Unk	Not Reported
Docusate	C	100 Mg	Not Reported
Senna Plus [Docusate Sodium; Sennoside A+B]	C	50/8.6 Mg	Not Reported
Enoxaparin	C	40 Mg	Not Reported
Famotidine	C	20 Mg	Not Reported
Guaifenesin	C	100/5	Not Reported
Loperamide	C	2mg/15ml	Not Reported
Ondansetron	C	4mg/2ml	Not Reported
Zinc Sulfate	C	220 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899305	DIRECT		OT			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen 500mg Po Q6h Prn			C				Not Reported
	Cefepime 1g Iv Daily			C				Not Reported
	Metronidazole 500mg Iv Q12h			C				Not Reported
	Tocilizumab 400mg Iv Once			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899317	DIRECT	Y	LT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Pneumonia; Respiratory Failure	Remdesivir			S				Not Reported
	Covid-19 Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899326	DIRECT	Y	OT			91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Erythema; Infusion Site Irritation; Infusion Site Reaction; Pruritus	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899334	DIRECT	Y	HO			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Increased	Remdesivir			S	Intravenous drip			Gilead
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899383	DIRECT	Y	DE			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Ineffective; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899394	DIRECT	Y	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 2g Iv Daily			C				Not Reported
	Enoxaparin 40mg Subcut Q24h			C				Not Reported
	Methyprednisolone 40mg Iv Q8h			C				Not Reported
	Tocilizumab 800mg Iv Once			C				Not Reported

		Fentanyl Infusion			C					Not Reported
		Norepinephrine Infusion			C					Not Reported
		Propofol Infusion			C					Not Reported
		Vecuronium			C					Not Reported
		Famotidine 20mg Po Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899404	DIRECT	Y	OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Ascorbic Acid 500mg Bid			C				Not Reported
	Aspirin 325mg Po Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 1g Iv Bid			C				Not Reported
	Enoxaparin 40mg Subcut Bid			C				Not Reported
	Famotidine 40mg Po Bid			C				Not Reported
	Insulin Glargine 15 Units Qbedtime			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Methylprednisolone 40mg Iv Bid			C				Not Reported
	Zinc Sulfate 220mg Bid			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899416	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bilirubin Conjugated Decreased; Hypotension; Pyrexia; Sepsis; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Albuterol Sulfate Hfa Inhaler			C				Not Reported
	Albuterol Nebulizer			C				Not Reported
	Epoprostenol-Floan			C				Not Reported

		Midazolam			C				Not Reported
		Insulin Regular			C				Not Reported
		Insulin Lispro			C				Not Reported
		Hydromorphone			C				Not Reported
		Heparin			C				Not Reported
		Omprazole			C				Not Reported
		Meropenam			C				Not Reported
		Linezolid			C				Not Reported
		Norepinephrine			C				Not Reported
		Lipase-Protease-Amylase			C				Not Reported
		Rocuronium			C				Not Reported
		Propofol			C				Not Reported
		Prismasol Bgk 2/3.5 Replacement Solution			C				Not Reported
		Magnesium Sulfate, Potassium Chloride In Prismasate Bgk 4/2.5 Dialysis			C				Not Reported
		Aspirin			C				Not Reported
		Lisinopril			C				Not Reported
		Sodium Phosphate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899424	DIRECT	Y	OT			91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecacliferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899429	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Respiratory	Remdesivir			S	Intravenous drip			Not Reported
	Albuterol-Ipratropium Inhalation			C				Not Reported

Failure	Solution			
	Amiodarone	C		Not Reported
	Cefepime 2g Iv Bid	C		Not Reported
	Docusate 100mg Po Bid	C		Not Reported
	Enoxaparin 40mg Subcut Bid	C		Not Reported
	Insulin Lispro Sliding Scale	C		Not Reported
	Methylprednisolone 40mg Iv Q12h	C		Not Reported
	Senna 8.6mg Po Daily	C		Not Reported
	Tocilizumab 400mg Once Scheduled	C		Not Reported
	Vancomycin 1500mg Iv Daily	C		Not Reported
	Amiodarone Drip	C		Not Reported
	Dexmedetomidine Drip	C		Not Reported
	Fentanyl Drip	C		Not Reported
	Heparin Drip	C		Not Reported
	Norepinephrine Drip	C		Not Reported
	Propofol Drip	C		Not Reported
	Vasopressin Drip	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899435	DIRECT	Y	OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol-Ipratropium			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Diltiazem			C				Not Reported
	Gabapentin			C				Not Reported
	Glimeperide			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Isosorbide Dinitrate			C				Not Reported
	Methylprednisolone			C				Not Reported
	Metoclopramide			C				Not Reported
	Pantoprazole			C				Not Reported

	Zinc			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899442	DIRECT	Y				56 YR	Transgender	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899447	DIRECT	Y	DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Continuous Haemodiafiltration	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Amiodarone Bolus And Infusion			C				Not Reported
	Aspirin Chewable 81mg Daily			C				Not Reported
	Atorvastatin 80mg Qhs			C				Not Reported
	Atracurium Infusion			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Dobutamine Infusion			C				Not Reported
	Epoprostenol Continuous Neb			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Heparin Infusion			C				Not Reported
	Vitamin C 1500mg Iv Q6h, Thiamine 200mg Iv Q12h			C				Not Reported
	Hydrocortisone 50mg Iv Q6h			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Phenylephrine Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Sodium Bicarbonate Infusion			C				Not Reported
	Vasopressin Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899460	DIRECT	Y	OT			90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899465	DIRECT	Y	DE			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899470	DIRECT	Y				68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Ischaemic Hepatitis; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Dextromethorphan			C				Not Reported
	Enoxaparin			C				Not Reported
	Gabapentin			C				Not Reported
	Acetominophen			C				Not Reported
	Lactulose			C				Not Reported
	Magnesiun Oxide			C				Not Reported
	Compazine			C				Not Reported
	Cisatracurium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17899481	DIRECT	Y				78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous drip		4 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900464	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip			Gilead
	Eculizumab			C				Not Reported
	Methylpredisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900481	DIRECT	N	OT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Infection; Gastric Fluid Analysis Abnormal; Gastrointestinal Obstruction; General Physical Health Deterioration	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuteral			C				Not Reported
	Amiodarone			C				Not Reported
	Amlodipine			C				Not Reported
	Ampicillin-Sulbactam			C				Not Reported
	Apixaban			C				Not Reported
	Atenolol			C				Not Reported
	Atorvastatin			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Chlorhexidine Gluconate			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Dextrose			C				Not Reported
	Digoxin			C				Not Reported
	Etomidate			C				Not Reported

		Famotidine			C					Not Reported
		Fentanyl			C					Not Reported
		Glucagon			C					Not Reported
		Glycopyrrolate			C					Not Reported
		Heparin			C					Not Reported
		Insulin Lispro Pen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900482	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Lip Oedema; Lip Swelling; Swollen Tongue; Tongue Oedema	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone 2 Gm			C				Not Reported
	Azithromycin 500 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900484	DIRECT	Y	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900489	DIRECT	Y	LT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900494	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Hepatic Failure	Remdesivir	Y	S	Intravenous drip	5 DAY	Gilead
	Propofol		C			Not Reported
	Morphine		C			Not Reported
	Lovenox		C			Not Reported
	Protonix		C			Not Reported
	Metoprolol		C			Not Reported
	Zithromax		C			Not Reported
	Ceftriaxone		C			Not Reported
	Norvasc		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900498	DIRECT	N	DE			7 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip		2 DAY	Gilead
	Rocephin			C				Not Reported
	Morphine			C				Not Reported
	Dopamine			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900502	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency: 200mg/D,100mg/D;		Gilead
	Azithromycin 500mg Iv Daily			C				Not Reported
	Cefepime 1g Iv Q8h			C				Not Reported
	Enoxaparin 40mg Subq Q24h			C				Not Reported
	Epoprostenol Continueous Neb			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Heparin Infusion			C				Not Reported
	Lantus 11 Units Qhs			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported

	Levothyroxine 88mcg Po Daily			C					Not Reported
	Midazolam Infusion			C					Not Reported
	Norepinephrine Infusion			C					Not Reported
	Pip/Tazo 4.5g Iv Q8h (Extended Infusion)			C					Not Reported
	Propofol Infusion			C					Not Reported
	Sodium Bicarbonate Infusion			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900505	DIRECT	Y	OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Enoxaparin 40mg Subq Qhs			C				Not Reported
	Paroxetine 40mg Daily			C				Not Reported
	Zolpidem 10mg Po Qhs Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900509	DIRECT	Y	HO, OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous drip	Other Frequency:One Time;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900514	DIRECT	Y				95 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

Issue	Azithromycin	C	Not Reported
	Ceftriaxone	C	Not Reported
	Metoprolol Tartrate	C	Not Reported
	Piperacillin / Tazobactam	C	Not Reported
	Magnesium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900528	DIRECT	Y	DE			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead
	Norepinephrine			C				Not Reported
	Sodium Bicarbnonate			C				Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Zosyn			C				Not Reported
	Morphine			C				Not Reported
	Cathflo Activase			C				Not Reported
	Atacarium			C				Not Reported
	Morphine			C				Not Reported
	Actemra			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2020	17900534	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip		2 DAY	Gilead
	Norepinephrine			C				Not Reported
	Protonix			C				Not Reported
	Morphine			C				Not Reported
	Propofol			C				Not Reported
	Bicarbonate			C				Not Reported
	Atorvastatin			C				Not Reported
	Midazolam			C				Not Reported
	Furosemide			C				Not Reported
	Rocephin			C				Not Reported
	Zithromax			C				Not Reported

		Lovenox			C					Not Reported
		Kionex			C					Not Reported
		Metoprolol			C					Not Reported
		Calcium Gluconate			C					Not Reported
		Lorazepam			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17810056	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0467380		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Death; Oliguria	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, 5 Mg/Ml Qd		Gilead
	Zosyn			S				Not Reported
	Vancomycin			S				Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Etomidate			C		Unk		Not Reported
	Succinylcholine Bromide			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Naloxone			C		Unk		Not Reported
	Piperacillin/Tazobactam			C		Unk		Not Reported
	Norepinephrine			C		90 Unk		Not Reported
	Epoprostenol			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Aspirin (E.C.)			C		Unk		Not Reported
	Bisacodyl Sandoz			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Insulin Lispro			C				Not Reported
	Propofol			C		Unk		Not Reported
	Senna Acutifolia			C		Unk		Not Reported
	Furosemide [Furosemide Sodium]			C	Intravenous (not otherwise specified)	40 Mg, Once		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

		Enoxaparin			C		Unk			Not Reported
		Heparin			C		Unk			Not Reported
		Metolazone			C		10 Mg			Not Reported
		Vasopressin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17837798	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468927		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	300 Mg, Total		Gilead
	Cefepime			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Methocarbamol			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Pregabalin			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Vasopressin			C		Unk		Not Reported
	Hydrocortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17841756	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468849		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Failure; Covid-19	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Zosyn	C		Unk		Not Reported
	Albuterol [Salbutamol]	C		Unk		Not Reported
	Insulin Lispro	C		Unk		Not Reported
	Insulin Glargine	C		Unk		Not Reported
	Combivent	C		Unk		Not Reported
	Amlodipine	C		Unk		Not Reported
	Precedex	C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]	C		Unk		Not Reported
	Gabapentin	C		Unk		Not Reported
	Seebri	C		Unk		Not Reported
	Levothyroxine	C		Unk		Not Reported
	Ativan	C		Unk		Not Reported
	Lopressor	C		Unk		Not Reported
	Dulera	C		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900566	DIRECT	Y				29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900583	DIRECT	Y				54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Infusion Site Pruritus	Remdesivir	Y	S	Intravenous (not otherwise specified)	5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900630	DIRECT	Y				72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Abrasion; Urticaria	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Furosemide			C				Not Reported
	Potassium Chloride			C				Not Reported
	Prinivil			C				Not Reported
	Acetaminophen Prn			C				Not Reported
	Enoxaparin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17900640	DIRECT	Y	OT			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901572	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0471292		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypermagnesaemia	Remdesivir			S	Unknown	Unk		Gilead
	Tocilizumab			C	Unknown			Not Reported
	Ccp			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901656	DIRECT	Y	OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Propofol Infusion			C				Not Reported
	Pantoprazole Iv			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901657	DIRECT	Y	DE			93 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Atrial Fibrillation; Cardio-Respiratory Arrest; Glomerular Filtration Rate Decreased; Pulmonary Embolism	Remdesivir Under Emergency Use Authorization (Eua)			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901658	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Cardio-Respiratory Arrest	Remdesivir			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901659	DIRECT	Y	OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir			S	Intravenous bolus			Gilead

Increased	Benzonate	C	Not Reported
	Guaifenesin	C	Not Reported
	Azithromycin	C	Not Reported
	Ceftriaxone	C	Not Reported
	Diphenhydramine	C	Not Reported
	Enoxaparin	C	Not Reported
	Melatonin	C	Not Reported
	Pantoprazole	C	Not Reported
	Acetamnophen	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17901955	EXPEDITED (15-DAY)			US-GILEAD-2020-0472521		27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17902266	EXPEDITED (15-DAY)			US-GILEAD-2020-0472466		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17904983	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470945		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905097	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470652		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905302	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0471308		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905508	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Not Reported
	Atorvastatin 10mg Po Qbedtime			C				Not Reported
	Carvedilol 12.5mg Po Bid			C				Not Reported
	Cefepime 2g Iv Q12h			C				Not Reported
	Daptomycin 700mg Iv Q24h			C				Not Reported
	Insulin Glargine 35 Units Subcut Bid			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Linezolid 600mg Iv Q12h			C				Not Reported
	Nifedipine Er 60mg Daily			C				Not Reported
	Heparin Drip			C				Not Reported
	Hydromorphone 1mg Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905511	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Meperidine			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Labetalol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Tamsulosin			C				Not Reported
	Levetiracetam			C				Not Reported
	Finasteride			C				Not Reported
	Amlodipine			C				Not Reported
	Metronidazole			C				Not Reported
	Enoxaparin			C				Not Reported
	Rivaroxaban			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Lorazepam			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Trazodone			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Acetaminophen			C				Not Reported
	Advil Pm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905516	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:One Time;		Gilead
	Azithromycin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Methylprednisone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905521	DIRECT	Y	DE			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatic Enzyme Increased; Refusal Of Treatment By Patient; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Clindamycin			C				Not Reported
	Methylprednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905527	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Flushing; Rash; Rash Erythematous; Respiratory Disorder	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905531	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Bilirubin Increased; Hepatic Enzyme Increased; Surgery; Therapy Interrupted	Remdesivir Eua			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905542	DIRECT	Y	DE			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Hepatic Steatosis; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Vancomycin			C				Not Reported
	Humalog Sliding Scale			C				Not Reported
	Propofol			C				Not Reported
	Esomeprzole			C				Not Reported
	Acorbic Acid			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Solumedrol Taper Dose			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Propranolol			C				Not Reported
	Lasix Drip			C				Not Reported
	Heparin Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Midazolam Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Rocuronium			C				Not Reported
	Metopropol			C				Not Reported
	Acetaminophine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905554	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous drip			Not Reported
	Ascorbic Acid 500mg Po Bid			C				Not Reported
	Aspirin 81mg Po Daily			C				Not Reported
	Enoxaparin 40mg Subcut Q24h			C				Not Reported
	Famotidine 20mg Po Bid			C				Not Reported

	Tocilizumab 800mg Iv Once	C	Not Reported
	Fentanyl Drip	C	Not Reported
	Norepinephrine Drip	C	Not Reported
	Propofol Drip	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2020	17905569	DIRECT	Y				47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Administration Site Extravasation; Infusion Site Pain; Infusion Site Swelling	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Sodium Chloride 0.9%			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17826572	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0467950		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Tubular Necrosis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C		400 Mg		Not Reported
	Heparin			C				Not Reported
	Enoxaparin			C				Not Reported
	Trimethobenzamide			C		200 Mg, Once		Not Reported
	Asa			C				Not Reported
	Insulin Lispro			C				Not Reported
	Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported
	Levothyroxine			C				Not Reported
	Ethacrynic Acid			C				Not Reported
	Metoprolol			C		Unk		Not Reported
	Tradipitant			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17831684	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0468502		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Pneumonia Viral; Renal Failure	Remdesivir			S	Unknown	200 Mg		Gilead
	Acetaminophen			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Aztreonam			C				Not Reported
	Calcium Chloride			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine			C				Not Reported
	Benadryl 24 D			C				Not Reported
	Famotidine			C				Not Reported
	Breo Ellipta			C				Not Reported
	Furosemide			C				Not Reported
	Hydrocortisone			C				Not Reported
	Isosorbide			C				Not Reported
	Labetalol			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Midazolam			C				Not Reported
	Singulair			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Kcl			C				Not Reported
	Rocuronium			C				Not Reported
	Verapamil			C				Not Reported
	Fentanyl			C				Not Reported
	Flolan			C				Not Reported
	Heparin			C				Not Reported
	Amiodarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17835874	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468237		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen	C	Oral	1000 Mg Q5h		Not Reported
	Dextromethorphan	C	Oral	30 Mg		Not Reported
	Benzonatate	C				Not Reported
	Enoxaparin	C				Not Reported
	Aspirin [Acetylsalicylic Acid]	C				Not Reported
	Ibuprofen	C	Oral	400 Mg		Not Reported
	Vitamin C [Ascorbic Acid]	C				Not Reported
	Zinc Sulfate	C				Not Reported
	Hydroxychloroquine	C				Not Reported
	Prednisone	C				Not Reported
	Albuterol Hfa	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907183	DIRECT	Y	HO, OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous drip			Gilead
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Tocilizumab			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Pantoprazole			C				Not Reported
	Albuterol			C				Not Reported
	Potassium Chloride			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907187	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury	Remdesivir	Y	S	Intravenous drip	Gilead
	Atorvastatin		C		Not Reported
	Docusate		C		Not Reported
	Enoxaparin		C		Not Reported
	Famotidine		C		Not Reported
	Lantus Insulin		C		Not Reported
	Lispro Insulin		C		Not Reported
	Regular Insulin		C		Not Reported
	Solu-Medrol		C		Not Reported
	Pantoprazole		C		Not Reported
	Rocuronium		C		Not Reported
	Sodium Bicarbonate		C		Not Reported
	Hydralazine		C		Not Reported
	0.5% Normal Saline		C		Not Reported
	D5 With Sodium Bicarbonate		C		Not Reported
	Fentanyl Drip		C		Not Reported
	Midazolam		C		Not Reported
	Norepinephrine		C		Not Reported
	Propofol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907202	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; General Physical Health Deterioration	Remdesivir Eua			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907208	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)		9 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907210	DIRECT	Y	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous drip			Gilead
	Remdesivir 200 Mg			C				Not Reported
	Remdesivir 100 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907216	DIRECT	Y	DE			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19 Pneumonia; Diabetic Ketoacidosis; Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907224	DIRECT	Y				68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Peripheral Swelling	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907227	DIRECT	Y	DE			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Amlodipine 2.5 Mg Po Daily			C				Not Reported
	Cholecalciferol Tablet 1000			C				Not Reported

	Units Po Daily								
	Cyanocobalamin 1000 Mcg Po Daily			C					Not Reported
	Dexamethasone 10 Mg Lv Daily			C					Not Reported
	Enoxapan'N 40 Mg Iv Q12h			C					Not Reported
	Levothyroxine 112 Mcg Po Daily			C					Not Reported
	Hydromorphone Pca			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907232	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead
	Aspirin 81 Mg Po Daily			C				Not Reported
	Cettriaxone 19 Iv Daily			C				Not Reported
	Chlorhexidine 0.12% Mouthwash 15ml			C				Not Reported
	Dexamethasone 6 Mg Lv Daily			C				Not Reported
	Famotidine 20 Mg Po Bid			C				Not Reported
	Furosemide 20 Mg Iv Q8h			C				Not Reported
	Metoclopramide 5 Mg Iv Q8h			C				Not Reported
	Mvi			C				Not Reported
	Senna Docusate Po Bid			C				Not Reported
	Vancomycin Lv			C				Not Reported
	Artificial Tears			C				Not Reported
	Dexmedetomidine Lv Cont Infusion			C				Not Reported
	Fentanyl Continuous Infusion			C				Not Reported
	Heparin Continue Infusion			C				Not Reported
	Insulin Continuous Infusion			C				Not Reported
	Midazolam Continuous Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907303	DIRECT	Y	DE			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir			S				Gilead
	Captopril			C				Not Reported

	Furosemide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17907768	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir 0.7 Mg/Ml	Y		S	Intravenous drip			Gilead
	Remdesivir 0.7 Mg/Ml	Y		S	Intravenous drip			Gilead
	Atorvastatin			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Lantus Insulin			C				Not Reported
	Lispro Insulin			C				Not Reported
	Regular Insulin			C				Not Reported
	Solu-Medrol			C				Not Reported
	Pantoprazole			C				Not Reported
	Rocuronium			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Hydralazine			C				Not Reported
	0.5% Normal Saline			C				Not Reported
	D5 With Sodium Bicarbonate			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908452	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472502		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk, Qd		Gilead
	Propofol			C		Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported

		Docusate;Senna			C		Unk			Not Reported
		Enoxaparin			C		Unk			Not Reported
		Pantoprazole			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908465	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472503		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Dreams; Hallucination; Suicidal Ideation	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Benzonatate			C		Unk		Not Reported
	Dextromethorphan			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Doxycycline			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Chlorhexidine			C	Oral	Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Labetalol			C		Unk		Not Reported
	Guaifenesin			C		Unk		Not Reported
	Nifedipine			C		Unk		Not Reported
	Norco			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Ondansetron			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908535	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0472755		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury	Remdesivir			S	Unknown	Unk			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908548	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472764			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17908571	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472816		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Replacement Therapy	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910859	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910866	DIRECT	Y	DS			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis	Remdesivir	Y		S	Intravenous drip			Gilead
	Doxycycline			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported

		Furosemide			C					Not Reported
		Vancomycin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910870	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous bolus		1 DAY	Gilead
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910874	DIRECT		OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910893	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemodialysis; Hypotension; Renal Impairment; Septic Shock	Remdesivir 5mg/Ml Injection - Eua			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir 5mg/Ml Injection - Eua			S	Intravenous drip			Gilead
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Gabapentin 100mg Po Daily			C				Not Reported
	Propofol Continuous Iv			C				Not Reported
	Phenyephrine Continuous Iv			C				Not Reported
	Midazolam Continuous Iv			C				Not Reported

		Aspirin 81mg Oral Daily			C					Not Reported
		Insulin Lispro Sq Per Protocol			C					Not Reported
		Acetaminophen 1g Iv Q6h Prn			C					Not Reported
		Famotidine 20mg Iv Daily			C					Not Reported
		Fentanyl Continuous Iv			C					Not Reported
		Furosemide 40mg Iv X 1			C					Not Reported
		Albumin 25% 25g Iv X 1			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910897	DIRECT	Y	OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910903	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Tylenol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Zofran			C				Not Reported
	Fentanyl			C				Not Reported
	Protonix			C				Not Reported
	Lovenox			C				Not Reported
	Methylprednisolone			C				Not Reported
	Robutussin			C				Not Reported
	Loperamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910907	DIRECT	Y				47 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:X 1 Dose;		Gilead
	Convalescent Plasma	C				Not Reported
	Colace 100 Mg Po Daily	C				Not Reported
	Duloxetine 60 Mg Po Daily	C				Not Reported
	Heparin 5000 Units Subq Q 8 Hours	C				Not Reported
	Culturelle 1 Po Daily	C				Not Reported
	Zosyn 2.25 G Q 6 Hours	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910919	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Critical Illness	Remdesivir			S				Gilead
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Albuterol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cisatracurium			C				Not Reported
	Vancomycin			C				Not Reported
	Rocuronium			C				Not Reported
	Propofol			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Pantoprazole			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Metoprolol			C				Not Reported
	Methylprednisolone			C				Not Reported
	Lorazepam			C				Not Reported
	Levofloxacin			C				Not Reported
	Hydromorphone			C				Not Reported
	Fentanyl			C				Not Reported
	Famotidine			C				Not Reported
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910922	DIRECT	Y	DS			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis	Remdesivir	Y		S	Intravenous drip			Gilead
	Enoxpapain			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910926	DIRECT	Y				81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Albumin 25%			C				Not Reported
	Unasyn 3gm			C				Not Reported
	Cefepime 2gm			C				Not Reported
	Digoxin 125mcg			C				Not Reported
	Etomidate 20mg			C				Not Reported
	Furosemide			C				Not Reported
	Linezolid 600mg			C				Not Reported
	Meropenem			C				Not Reported
	Metolazone			C				Not Reported
	Metoprolol			C				Not Reported
	Metronidazole			C				Not Reported
	Midazolam			C				Not Reported
	Potassium Chloride			C				Not Reported
	Succinylcholine			C				Not Reported
	Morphine			C				Not Reported
	Clinimix			C				Not Reported
	Diltiazem Drip			C				Not Reported
	Heparin Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910931	DIRECT	Y	LT, OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Continuous Haemodiafiltration; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17910936	DIRECT	Y	DS, HO, OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anuria; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead
	Ampicillin-Sulbactam Iv			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Dexmedetomidine Infusion			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Rocuronium Injection			C				Not Reported
	Tocilizumab Injection			C				Not Reported
	Vancomycin Injection			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17911462	DIRECT	Y	DE			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Pulse Absent; Ventricular Tachycardia	Remdesivir Eua			S	Intravenous (not otherwise specified)		2 HR	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2020	17911526	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased	Remdesivir, 0.7mg/Ml	Y		S	Intravenous drip			Gilead
	Atorvastatin			C				Not Reported

			Docusate			C					Not Reported
			Enoxaparin			C					Not Reported
			Famotidine			C					Not Reported
			Lantus Insulin			C					Not Reported
			Lispro Insulin			C					Not Reported
			Regular Insulin			C					Not Reported
			Solu-Medrol			C					Not Reported
			Pantoprazole			C					Not Reported
			Rocuronium			C					Not Reported
			Sodium Bicarbonate			C					Not Reported
			Hydralazine			C					Not Reported
			0.5% Normal Saline			C					Not Reported
			D5 With Sodium Bicarbonate			C					Not Reported
			Fentanyl Drip			C					Not Reported
			Midazolam			C					Not Reported
			Norepinephrine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17805184	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	US-GILEAD-2020-0466961		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hepatic Function Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Metformin			C				Not Reported
	Atorvastatin			C				Not Reported
	Atropine			C				Not Reported
	Ceftazidime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dextrose			C				Not Reported
	Midazolam			C				Not Reported
	Morphine			C				Not Reported
	Naloxone			C				Not Reported
	Neostigmine			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Rocuronium			C				Not Reported
	Vancomycin			C				Not Reported
	Vasopressin			C				Not Reported
	Hydrocortisone			C	Intravenous (not	100 Mg		Not Reported

						otherwise specified)				
		Epinephrine			C					Not Reported
		Fentanyl Abz			C					Not Reported
		Lorazepam			C					Not Reported
		Propofol			C					Not Reported
		Flumazenil			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17835872	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468272		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin			C				Not Reported
	Potassium			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17842534	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468511		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

Aminotransferase Increased	Acetaminophen	C	Not Reported
	Albuterol Hfa	C	Not Reported
	Hypromellose	C	Not Reported
	Benzocaine	C	Not Reported
	Benzonatate	C	Not Reported
	Bisacodyl	C	Not Reported
	Ceterezol	C	Not Reported
	Docusate	C	Not Reported
	Enoxaparin	C	Not Reported
	Guaifenesin	C	Not Reported
	Hydrocodone Bitartrate And Acetaminophen	C	Not Reported
	Albuterol;Ipratropium	C	Not Reported
	Melatonin	C	Not Reported
	Morphine	C	Not Reported
	Ondansetron	C	Not Reported
	Pantoprazole	C	Not Reported
	Simethicone	C	Not Reported
	Sodium Chloride	C	Not Reported
	Tramadol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17844495	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468824		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Covalescent Plasma			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Chlorhexidine			C				Not Reported
	Olanzapine			C				Not Reported
	Pantoprazole			C				Not Reported

	Potassium Chloride			C						Not Reported
	Acetaminophen			C						Not Reported
	Hyaluronidase			C						Not Reported
	Sodium Phosphate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17848043	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469167		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Convalescent Plasma			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Escitalopram			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Polycarbophil			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Acetaminophen			C				Not Reported
	Alprazolam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17868205	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469507		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pyrexia; Ventricular Tachycardia	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Acetaminophen	C		Unk	Not Reported
	Amlodipine	C			Not Reported
	Apixaban	C			Not Reported
	Aspirin (E.C.)	C			Not Reported
	Atorvastatin	C			Not Reported
	Benztropine [Benzatropine]	C			Not Reported
	Carvedilol	C			Not Reported
	Divalproex	C			Not Reported
	Donepezil	C			Not Reported
	Famotidine	C			Not Reported
	Furosemide	C			Not Reported
	Guaifenesin	C			Not Reported
	Insulin Glargine	C			Not Reported
	Insulin Regular Hm	C			Not Reported
	Ipratropium Bromide And Albuterol Sulfate	C			Not Reported
	Loratadine	C			Not Reported
	Methylprednisolone Sodium Succinate	C			Not Reported
	Montelukast	C			Not Reported
	Ibrutinib	C			Not Reported
	Pantoprazole	C			Not Reported
	Quetiapine	C			Not Reported
	Tamsulosin	C			Not Reported
	Zinc Sulfate	C			Not Reported
	Zosyn	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17873038	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469296		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910335	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472813		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Piperacillin & Tazobactam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910451	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0473164		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Creatinine Renal Clearance Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17910487	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473079		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912038	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912045	DIRECT	Y				62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Incorrect Dose Administered	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912177	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Cefepime			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Etomidate			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Humulin N			C				Not Reported
	Humulin R			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Ondansetron			C				Not Reported
	Propofol			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17912699	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473172		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

		Ceftriaxone			C					Not Reported
		Azithromycin			C					Not Reported
		Convalescent Plasma			C					Not Reported
		Enoxaparin			C					Not Reported
		Paroxetine			C					Not Reported
		Zolpidem			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913269	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473152		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hypotension; Hypoxia	Remdesivir			S	Unknown	Unk		Gilead
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17913808	EXPEDITED (15-DAY)			US-GILEAD-2020-0471183		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Malfunction	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914120	EXPEDITED (15-DAY)			US-GILEAD-2020-0468293		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Acetaminophen			C		650 Mg, Prn		Not Reported
	Aquaphor Healing			C	Topical	Unk		Not Reported
	Cholecalciferol			C	Oral	1000 U		Not Reported
	Citalopram			C		15 Mg, Qhs		Not Reported
	Citalopram			C				Not Reported
	Albuterol Hfa			C	Respiratory	2 Puffs		Not Reported

					(inhalation)			
		Trazodone		C	Oral	25 Mg		Not Reported
		Dextrose & Sodium Chloride		C	Intravenous (not otherwise specified)	1000 Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914752	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0472809		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Electrocardiogram St Segment Elevation; Hypotension; Pulseless Electrical Activity; Shock; Sinus Tachycardia; Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Aspirin Ec			C		Unk		Not Reported
	Chlorhexidine			C		Unk		Not Reported
	Chlorhexidine			C		Unk		Not Reported
	Enoxaparin			C		40 Mg, Qd		Not Reported
	Enoxaparin			C		50 Unk		Not Reported
	Enoxaparin			C		100 Unk		Not Reported
	Etomidate			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Fluticasone Furoate			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Glycopyrrolate [Glycopyrronium]			C		Unk		Not Reported
	Insulin Aspart			C		Unk		Not Reported
	Lidocaine			C		Unk		Not Reported
	Mupirocin			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported

						Propofol	C	Unk		Not Reported
						Senna [Senna Alexandrina]	C	Unk		Not Reported
						Tamsulosin	C	Unk		Not Reported
						Tiotropium	C	Unk		Not Reported
						Tocilizumab	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914772	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473016		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Eye Irritation; Pruritus	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Apixaban			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Guaifenesin			C				Not Reported
	Pantoprazole			C		Unk		Not Reported
	Fluticasone;Vilanterol			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Vitamin C [Ascorbic Acid]			C		Unk		Not Reported
	Vitamin D [Colecalciferol]			C		Unk		Not Reported
	Albuterol;Ipratropium			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914891	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473119		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914932	EXPEDITED (15-DAY)			US-GILEAD-2020-0472409		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914935	EXPEDITED (15-DAY)			US-GILEAD-2020-0472420		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914942	EXPEDITED (15-DAY)			US-GILEAD-2020-0472425		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914944	EXPEDITED (15-DAY)			US-GILEAD-2020-0472430		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

	Remdesivir				S	Intravenous (not otherwise specified)	100 Unk			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914946	EXPEDITED (15-DAY)			US-GILEAD-2020-0472433		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914950	EXPEDITED (15-DAY)			US-GILEAD-2020-0472462		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914962	EXPEDITED (15-DAY)			US-GILEAD-2020-0472474		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914964	EXPEDITED (15-DAY)			US-GILEAD-2020-0472486		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914965	EXPEDITED (15-DAY)			US-GILEAD-2020-0472480		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914967	EXPEDITED (15-DAY)			US-GILEAD-2020-0472504		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17914972	EXPEDITED (15-DAY)			US-GILEAD-2020-0472507		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915858	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

	Vancomycin			C					Not Reported
	Crestor			C					Not Reported
	Azithromycin			C					Not Reported
	Cisatracurium			C					Not Reported
	Propofol			C					Not Reported
	Terazosin			C					Not Reported
	Cefepime			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915865	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Hypersensitivity; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915873	DIRECT	Y				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir Under Emergency Use Authorization (Eua)	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915881	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Throat Tightness	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Amitryptiline			C				Not Reported

		Amphetamine-Dextroamphetamine			C						Not Reported
		Citalopram			C						Not Reported
		Clonazepam			C						Not Reported
		Montelukast			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915886	DIRECT	Y				36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915949	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Dialysis	Remdesivir	Y		S	Intravenous drip			Gilead
	Coreg			C				Not Reported
	Lisinopril			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Zinc			C				Not Reported
	Azithromycin			C				Not Reported
	Ns			C				Not Reported
	Albumin 25%			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915955	DIRECT	Y	DE			84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Azotaemia; Hypotension; Lung Consolidation; Paralysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

			Remdesivir	Y		S	Intravenous (not otherwise specified)		Gilead
			Heparin Drip			C			Not Reported
			Percedex Drip			C			Not Reported
			Fentanyl Drip			C			Not Reported
			Midazolam Drip			C			Not Reported
			Norepinephrine			C			Not Reported
			Propofol			C			Not Reported
			Rocuronium			C			Not Reported
			Humalog Sliding Scale			C			Not Reported
			Esomeprazole			C			Not Reported
			Ascobic Acid			C			Not Reported
			Seleniun			C			Not Reported
			Zinc			C			Not Reported
			Tpn			C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915963	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Condition Aggravated; Dialysis; Hypoxia; Lung Consolidation; Multiple Organ Dysfunction Syndrome; Pseudomonas Test Positive; Respiratory Acidosis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Apixabn			C				Not Reported
	Heparin			C				Not Reported
	Docusate			C				Not Reported
	Humalog Sliding Scale			C				Not Reported
	Meropenem			C				Not Reported
	Seroquel			C				Not Reported
	Vancomycin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ascobic Acid			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Ativan			C				Not Reported
	Selenium			C				Not Reported
	Versed			C				Not Reported
	Norepineohrine			C				Not Reported

		Rocuronium			C					Not Reported
		Cefepime			C					Not Reported
		Vitamin D3			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915988	DIRECT	Y				43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Macular	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17915997	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Glomerular Filtration Rate Decreased; Renal Impairment; Respiratory Failure; Septic Shock	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2020	17916329	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir Injection 100 Mg/Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Injection 100 Mg/Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Brimonidine			C				Not Reported

	Enoxaparin			C						Not Reported
	Famotidine			C						Not Reported
	Hydroxychloroquine			C						Not Reported
	Lantus Insulin			C						Not Reported
	Humalog Insulin			C						Not Reported
	Latanoprost			C						Not Reported
	Solu-Medrol			C						Not Reported
	Oseltamivir			C						Not Reported
	Zosyn			C						Not Reported
	Zinc Sulfate			C						Not Reported
	Tamsulosin			C						Not Reported
	Ziprasidone			C						Not Reported
	Hydralazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17847986	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469172		92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead
	Ativan			C				Not Reported
	Morphine			C				Not Reported
	Glycopyrrolate [Glycopyrronium Bromide]			C				Not Reported
	Hydromorphone			C				Not Reported
	Unasyn Im/Iv			C				Not Reported
	Haldol Decan			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17868197	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469457		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Dehydration; Hypotension; Syncope	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa			C		Unk		Not Reported

	Ascorbic Acid	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Tussionex [Hydrocodone; Phenyltoloxamine]	C		Not Reported
	Solu-Medrol	C	Unk	Not Reported
	Sodium Chloride 0.9%	C		Not Reported
	Thiamine	C	Unk	Not Reported
	Zinc Sulfate [Zinc Sulfate Monohydrate]	C	Unk	Not Reported
	Chlorhexidine	C	Unk	Not Reported
	Famotidine	C	Unk	Not Reported
	Mupirocin	C	Unk	Not Reported
	Morphine	C	Unk	Not Reported
	Acetaminophen	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17901688	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0471284		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypermagnesaemia	Remdesivir			S	Unknown	Unk		Gilead
	Remdesivir			S				Gilead
	Lasix [Furosemide Sodium]			C				Not Reported
	Ccp			C				Not Reported
	Tocilizumab Recombinant			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916163	DIRECT	Y	HO			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916168	DIRECT	Y	HO			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Urea Increased; Hepatic Enzyme Increased; Respiratory Disorder	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916319	DIRECT	Y				46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Nausea	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916363	DIRECT	Y				59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Disorder	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17916633	DIRECT	Y				54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir	Y		S	Intravenous drip			Gilead

	Acetaminophen	C			Not Reported
	Albuterol Hfa	C			Not Reported
	Ascorbic Acid 500 Mg	C			Not Reported
	Benzonatate 100 Mg	C			Not Reported
	Dextromethorphan-Guaifenesin 10-100	C			Not Reported
	Enoxaparin 40 Mg	C			Not Reported
	Metformin 1000 Mg	C			Not Reported
	Tocilizumab 400 Mg	C			Not Reported
	Insulin Lispro	C			Not Reported
	Levothyroxine 75 Mcg	C			Not Reported
	Oxymetazoline Nasal Spray	C			Not Reported
	Zinc Sulfate 220 Mg	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17917085	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473734		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bilirubin Conjugated Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Sodium Phosphate			C				Not Reported
	Lisinopril			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Magnesium Sulfate;Potassium Chloride			C				Not Reported
	Prismasol			C				Not Reported
	Rocuronium			C				Not Reported
	Propofol			C				Not Reported
	Lipase			C				Not Reported
	Norepinephrine			C				Not Reported
	Linezolid			C				Not Reported
	Meropenem			C				Not Reported
	Omprazole			C				Not Reported
	Heparin			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Regular Beef			C				Not Reported

			Midazolam			C					Not Reported
			Epoprostenol [Epoprostenol Sodium]			C					Not Reported
			Albuterol Sulfate Hfa			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17918257	EXPEDITED (15-DAY)			US-GILEAD-2020-0472481		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17918557	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468535		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Gastrointestinal Haemorrhage; Haematochezia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydromorphone			C				Not Reported
	Acetaminophen			C				Not Reported
	Zofran [Ondansetron]			C				Not Reported
	Vitamin D3			C				Not Reported
	Titralac [Calcium Carbonate]			C				Not Reported
	Seroquel			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Miralax			C				Not Reported
	Benadryl			C				Not Reported
	Levophed			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Potassium Chloride			C				Not Reported
	Clozaril			C				Not Reported
	Propofol			C				Not Reported
	Amidate [Etomidate]			C				Not Reported

	Quelicin	C				Not Reported
	Fentanyl	C				Not Reported
	Versed	C				Not Reported
	Humulin	C				Not Reported
	Humalog	C				Not Reported
	Ancef [Ceftriaxone Sodium]	C				Not Reported
	Protonix [Omeprazole]	C				Not Reported
	Flagyl [Metronidazole]	C				Not Reported
	Rocephin [Ceftriaxone]	C				Not Reported
	Vancomycin	C				Not Reported
	Zenpep	C				Not Reported
	Prilosec [Omeprazole]	C				Not Reported
	Potassium Bicarbonate	C				Not Reported
	Zemuron	C				Not Reported
	Convalescent Plasma	C		Unk		Not Reported
	Levaquin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17919219	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473354		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Decreased; Death; Renal Failure	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17919225	EXPEDITED (15-DAY)			US-GILEAD-2020-0473117		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17919515	EXPEDITED (15-DAY)			US-GILEAD-2020-0473064		5 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Incorrect Product Dosage Form Administered; Off Label Use	Remdesivir			S	Intravenous (not otherwise specified)	2.5 Mg/Kg, Qd			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17919730	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473961		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921943	DIRECT	Y	HO			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Liver Function Test Increased; Maternal Exposure During Pregnancy; Transaminases Increased	Remdesivir Via Eua			S	Intravenous bolus			Gilead
	Piperacillin-Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921949	DIRECT	Y	DE			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Thrombocytopenia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Vancomycon			C				Not Reported
	Omnipaque 350 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921951	DIRECT	Y	OT			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Cessation; Transaminases Increased	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921956	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palliative Care	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921960	DIRECT	Y	DE			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; General Physical Health Deterioration; Rhabdomyolysis	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:1 Time Dose;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921964	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity; Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Atorvastatin			C				Not Reported
	Cholecalciferol			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Hydrocortisone			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Valproic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921966	DIRECT	Y	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Ventricular Tachycardia	Remdesivir For Emergency Use Authorization			S	Intravenous drip		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921972	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921986	DIRECT	Y	DE			95 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17921992	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Pruritus; Rash	Remdesivir			S	Intravenous drip	Other Frequency:Once;	5 DAY	Gilead
	Guaifenesin			C				Not Reported
	Enoxaparin			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17922004	DIRECT	Y	OT			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Gilead
	Clonazepam			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Midazolam			C				Not Reported
	Tocilizumab			C				Not Reported
	Vecuronium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17922013	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Faeces Discoloured	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17922039	DIRECT	Y	DE			94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17922045	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Enoxaparin 110mg Sc Q12h			C				Not Reported
	Famotidine 20mg Iv Bid			C				Not Reported

Creatinine Increased	Fentanyl Infusion			C					Not Reported
	Hydroxychloroquine			C					Not Reported
	Norepinephrine Infusion			C					Not Reported
	Piperacillin-Tazobactam			C					Not Reported
	Propofol Infusion			C					Not Reported
	Vancomycin Iv			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17922077	DIRECT	Y	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Ceftriaxone 1g Ivpb			C				Not Reported
	Colchicine 0.6mg			C				Not Reported
	Probenacid 500mg			C				Not Reported
	Enoxaparin 40mg			C				Not Reported
	Hydrocortisone 50mg			C				Not Reported
	Duoneb			C				Not Reported
	Ondansetron 4mg			C				Not Reported
	Promethazine 12.5mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17922091	DIRECT	Y				21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Not Reported
	Enoxaparin			C				Not Reported
	Flovent Hfa			C				Not Reported
	Ondansetron			C				Not Reported
	Guiafenesin			C				Not Reported
	Senna-Docusate			C				Not Reported
	Albuterol Hfa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17922096	DIRECT					68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17922100	DIRECT	Y	OT			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S				Gilead
	Methylprednisolone			C				Not Reported
	Enoxparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Losartan			C				Not Reported
	Doxycycline			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2020	17922121	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir	Y		S			7 DAY	Gilead
	Vancomycin			C				Not Reported
	Cefepime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17922104	DIRECT		OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2020	17922192	DIRECT	Y	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	17922080	DIRECT	Y				37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Remdesivir Eua Solution			S	Intravenous drip			Gilead
	Enoxaparin 40 Mg Sq Daily			C				Not Reported
	Filgastim 480 Mcg Once			C				Not Reported
	Topiramate 50 Mg Qday			C				Not Reported
	Zinc Sulfate 220 Mg Qday			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	17922087	DIRECT	Y				92 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir Eua Solution			S	Intravenous drip			Gilead
	Aspirin 81 Mg Daily			C				Not Reported
	Atorvastatin 80 Mg			C				Not Reported
	Carvedilol 6.25 Mg			C				Not Reported
	Enoxaparin 40 Mg Sq			C				Not Reported
	Furosemide 40 Mg X 1			C				Not Reported
	Pantoprazole 40 Mg Daily			C				Not Reported
	Piperacillin/Tazobactam 2.25g Q6h			C				Not Reported
	Potassium Chloride 40 Meq Q4h			C				Not Reported
	Vancomycin 1 Gm X 1			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	17922109	DIRECT	Y	HO			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Condition Aggravated	Remdesivir Eua Solution			S	Intravenous drip			Gilead
	Baclofen 5 Mg Ttid			C				Not Reported
	Gabapentin 300 Mg Qpm			C				Not Reported
	Heparin Sq Tid			C				Not Reported
	Midodrine 10 Mg Tid			C				Not Reported
	Piperacillin/Tazobactam 3.375g Q8h			C				Not Reported
	Vancomycin 1.25g Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	17922134	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Condition Aggravated	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	17922135	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once, Then 100mg;		Gilead
	Albuterol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Aspirin			C				Not Reported
	Lovenox			C				Not Reported
	Finasteride			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lopressor			C				Not Reported
	Oxycodone			C				Not Reported
	Tamsulosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	17922138	DIRECT	Y				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Exposure During Pregnancy; Foetal Heart Rate Abnormal; Gestational Diabetes; High Risk Pregnancy; Premature Labour	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Zithmax			C				Not Reported
	Rocephin			C				Not Reported
	Lovenox			C				Not Reported
	Insuin Sliding Scale			C				Not Reported
	Labetadol			C				Not Reported
	Prenatal Vitamin			C				Not Reported
	Ursodiol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2020	17922140	DIRECT	Y	OT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Remdesivir			S	Intravenous bolus	Other Frequency:One Time;		Not Reported
	Lovenox			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17892600	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470905		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Generalised Oedema	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Simethicone			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17922259	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Injection Site Extravasation	Remdesivir			S	Intravenous drip	Other Frequency:Once;	5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923114	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473800		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Docusate			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Lispro Insulin			C		Unk		Not Reported
	Insulin Regular Hm			C		Unk		Not Reported
	Solu-Medrol			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Rocuronium			C		Unk		Not Reported
	Sodium Bicarbonate			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Normal Saline			C		Unk		Not Reported
	D5 With Sodium Bicarbonate			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported

	Propofol			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923759	DIRECT	Y	DE			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923785	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Albuterol Hfa			C				Not Reported
	Acetaminophen			C				Not Reported
	Robitussin Ac			C				Not Reported
	Lovenox			C				Not Reported
	Solumedrol			C				Not Reported
	Lasix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923803	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923809	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923814	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Haemodialysis; Urine Output Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Initial Dose;		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported
	Atorvostatin Oral			C				Not Reported
	Fenobirate Oral			C				Not Reported
	Dexamethasone Iv			C				Not Reported
	Norepinephrine Iv Infusion			C				Not Reported
	Midazolam Iv Infusion			C				Not Reported
	Hydromorphone Iv Infusion			C				Not Reported
	Rocuronium Iv Infusion			C				Not Reported
	Fentanyl Iv			C				Not Reported
	Propofol Infusion			C				Not Reported
	Famotidine Iv			C				Not Reported
	Acetaminophen Tablet			C				Not Reported
	Phenobarbital Inj Iv			C				Not Reported
	Potassium Bicarb-Citric Acid Tablet			C				Not Reported
	Insulin Regular Infusion			C				Not Reported
	Etomidate Iv			C				Not Reported
	Aspirin Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923823	DIRECT	Y	DE			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Disease Progression	Remdesivir	Y		S	Intravenous bolus			Gilead
	Azithromycin			C				Not Reported
	Buproprion			C				Not Reported
	Buspirone			C				Not Reported

			Ceftriaxone			C					Not Reported
			Fentanyl			C					Not Reported
			Hydrocortisone			C					Not Reported
			Pantoprazole			C					Not Reported
			Propofol			C					Not Reported
			Norepinephrine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17923855	DIRECT	Y	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17924892	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0474386		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol Hfa			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Benzonatate			C				Not Reported
	Dextromethorphan Hbr & Guaifenesin			C				Not Reported
	Enoxaparin			C				Not Reported
	Metformin			C				Not Reported
	Tocilizumab			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levothyroxine			C				Not Reported
	Oxymetazoline			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925092	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0473804		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Metronidazole			C				Not Reported
	Vancomycin			C		Unk		Not Reported
	Meperidine [Pethidine Hydrochloride]			C		Unk		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Labetalol			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Tamsulosin			C		Unk		Not Reported
	Levetiracetam			C		Unk		Not Reported
	Finasteride			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Metronidazole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Rivaroxaban			C		Unk		Not Reported
	Albuterol [Salbutamol Sulfate]			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Cyclobenzaprine			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Multivitamin [Vitamins Nos]			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Advil Pm [Diphenhydramine Citrate;Ibuprofen]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17925342	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0474408		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead
	Clonazepam			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Epoprostenol			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Vecuronium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928219	DIRECT	Y	OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928222	DIRECT		DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Cardiogenic Shock	Remdesivir	S	Intravenous drip		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928224	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928230	DIRECT	Y	HO, LT			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Furosemide 80mg Po Qam			C				Not Reported
	Lisinopril 40mg Po Qam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928233	DIRECT	Y	HO			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Gilead
	Dexamethasone 6mg Once Daily Po			C				Not Reported
	Cefepime 1gm Every 24 Hours Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928237	DIRECT	Y				48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous bolus			Not Reported
	Rosuvastatin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Tocilizumab			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928253	DIRECT	Y	HO			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Culture Positive; Candida Test Positive	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)			Genentech
	Tocilizumab			C				Not Reported
	Dexamethasone 10mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928265	DIRECT					67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928273	DIRECT	Y	OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Ascorbic Acid 1000 Mg Po Bid			C				Not Reported
	Azithromycin 500 Mg Daily			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin 40 Mg Daily			C				Not Reported
	Iohexol			C				Not Reported
	Acetaminophen 650 Mg X1 Dose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928290	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Pulmonary Function Test Decreased; Shock	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amiodarone			C				Not Reported
	Apixiban			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Fuorsemide			C				Not Reported
	Propofol			C				Not Reported
	Cisatricurium			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Phenylephrine			C				Not Reported
	Dexamethasone			C				Not Reported
	Vasopressin			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928301	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Gilead
	Albuterol Nebulizer			C				Not Reported
	Azithromycin			C				Not Reported

	Cefepime	C	Not Reported
	Ceftriaxone	C	Not Reported
	Dexamethasone	C	Not Reported
	Plasma-Lyte-A	C	Not Reported
	Enoxaparin	C	Not Reported
	Finasteride	C	Not Reported
	Insulin (Long Acting, Short Acting, And Infusion)	C	Not Reported
	Linezolid	C	Not Reported
	Lorazepam	C	Not Reported
	Olanzapine	C	Not Reported
	Pantoprazole	C	Not Reported
	Senna/Docusate	C	Not Reported
	Tamsulosin	C	Not Reported
	Potassium Chloride	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2020	17928545	DIRECT	Y	RI			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir 100 Mg			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17842544	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468274		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Erythema; Heart Rate Increased; Hyperhidrosis; Nausea; Oxygen Saturation Decreased; Respiratory Rate Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17857266	EXPEDITED (15-DAY)			US-GILEAD-2020-0468544		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Issue	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17872272	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0469302		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Unknown	200 Mg		Gilead
	Remdesivir			S	Unknown	100 Mg		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Dopamine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17896650	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0472197		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Myocardial Infarction; Acute Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

Syndrome; Acute Respiratory Failure; Arrhythmia; Cardiomyopathy; Death; Ischaemic Hepatitis; Respiratory Distress	Aspirin [Acetylsalicylic Acid; Ascorbic Acid]	C	Unknown	81 Mg	Not Reported
	Penicillin [Benzylpenicillin Potassium]	C			Not Reported
	Amiodarone	C	Intravenous bolus	Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Atracurium	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported
	Dobutamine	C		Unk	Not Reported
	Epoprostenol	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Heparin	C		Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
	Hydrocortisone	C		Unk	Not Reported
	Midazolam	C		Unk	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Phenylephrine	C		Unk	Not Reported
	Propofol	C		Unk	Not Reported
	Sodium Bicarbonate	C		Unk	Not Reported
	Vasopressin	C		Unk	Not Reported
	Famotidine	C		Unk	Not Reported
	Thiamine	C		Unk	Not Reported
	Insulin Lispro	C		Unk	Not Reported
	Metoprolol Tartrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930765	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474819		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not	200 Mg, Once		Gilead

						otherwise specified)			
	Ceftriaxone			C		Unk			Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk			Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk			Not Reported
	Finasteride			C		Unk			Not Reported
	Insulin Lispro			C		Unk			Not Reported
	Lopressor			C		Unk			Not Reported
	Oxycodone			C		Unk			Not Reported
	Tamsulosin			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930918	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474713		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Covid-19; Hepatic Enzyme Increased; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			C		Unk		Not Reported
	Clindamycin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17930929	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472715		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Lasix [Furosemide]			C				Not Reported
	Tocilizumab			C				Not Reported
	Solu-Medrol			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Montelukast			C				Not Reported

					Atorvastatin		C				Not Reported
					Azithromycin		C				Not Reported
					Zinc Sulfate		C				Not Reported
					Enoxaparin		C				Not Reported
					Humalog		C				Not Reported
					Pantoprazole		C				Not Reported
					Meropenem		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17931108	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0474396		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk, Qd		Gilead
	Piperacillin & Tazobactam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17933002	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474849		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C				Not Reported
	Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17933440	EXPEDITED (15-DAY)		DE	US-GILEAD-2020-0474844		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Oxygen Therapy	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Bupropion			C		Unk		Not Reported

Buspirone	C	Unk	Not Reported
Ceftriaxone	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Hydrocortisone	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Warfarin	C		Not Reported
Prednisone	C		Not Reported
Albuterol [Salbutamol]	C		Not Reported
Levaquin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934300	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934303	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Renal Impairment	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934307	DIRECT	Y				46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934311	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Cessation; Transaminases Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934317	DIRECT	Y	HO			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Liver Function Test Increased	Remdesivir, 100 Mg			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934320	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Respiratory Acidosis	Remdesivir	Y		S	Intravenous bolus			Gilead
	Amlodipine			C				Not Reported
	Omeprazole			C				Not Reported
	Epoetin Alfa-Epbx			C				Not Reported
	Cinacalcet			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Ventolin			C				Not Reported
	Allopurinol			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Actemra			C				Not Reported
	Normal Saline Ivf			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Apresoline			C				Not Reported
	Atrovent			C				Not Reported
	Bumetanide			C				Not Reported
	Losartan			C				Not Reported

		Apixaban			C					Not Reported
		Lipitor			C					Not Reported
		Lopressor			C					Not Reported
		Enoxaparin			C					Not Reported
		Potassium Chloride			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934326	DIRECT	Y				54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dialysis; Respiratory Failure	Remdesivir			S				Not Reported
	Chlorhexidine Topical			C				Not Reported
	Omeprazole			C				Not Reported
	Acetaminophen			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Heparin			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Rocronium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934330	DIRECT	Y	DE			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospice Care	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Cefepime			C				Not Reported
	Chlorhexidine Topical			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Metronidzole			C				Not Reported
	Mupirocin (Nasal)			C				Not Reported
	Potassium Phosphate			C				Not Reported
	Vancomycin Iv			C				Not Reported
	Norephrinepine			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934335	DIRECT	Y				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted; Transaminases Increased	Remdesivir Injection	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934340	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Device Occlusion; Face Oedema; Haemodialysis; International Normalised Ratio Increased; Oxygen Saturation Abnormal; Renal Impairment; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg X 1, 100mg/D;		Gilead
	Acetaminophen 650mg Po Q6h Prn			C				Not Reported
	Albumin 5% 12.5g Iv Once			C				Not Reported
	Amlodipine 10mg Po Daily			C				Not Reported
	Aspirin Chew 81mg Po Daily			C				Not Reported
	Atorvastatin 20mg Po Qhs			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Cefepime 1g Iv Q24h			C				Not Reported
	Dexamethasone 6mg Iv Q24h			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Enoxaparin 40mg Subq Q24h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Furosemide 40mg And 80mg Iv			C				Not Reported
	Heparin 7500 Units Q8h			C				Not Reported
	Hydrochlorothiazide 12.5mg Po Daily			C				Not Reported
	Lantus Subq Qhs			C				Not Reported
	Insulin Lispro Sliding Scale 5x/Day			C				Not Reported
	Levothyroxine 88mcg Po Daily			C				Not Reported

		Propofol Infusion			C						Not Reported
		Midazolam Infusion			C						Not Reported
		Norepinephrine Infusion			C						Not Reported
		Pip/Tazo			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934369	DIRECT	Y	OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone 2 Grams Q24			C				Not Reported
	Doxycycline 100 Mg Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934375	DIRECT	Y				26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Therapy Interrupted	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934391	DIRECT	Y				56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Creatine Increased; Dyspnoea; Glomerular Filtration Rate Decreased; Sars-Cov-2 Test Positive; Septic Shock	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Atracurium			C				Not Reported
	Senna/Colace			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Lispro Insulin			C				Not Reported
	Oxycodone			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported

	Heparin			C						Not Reported
	Hydromorphone			C						Not Reported
	Midazolam			C						Not Reported
	Norepinephrine			C						Not Reported
	Propofol			C						Not Reported
	Vasopressin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934397	DIRECT	Y	DE			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Disease Progression; Pneumonia; Respiratory Failure; Respiratory Failure; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934404	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Sedation; Wheezing	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine			C				Not Reported
	Propofol			C				Not Reported
	Midazolam			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934408	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Ampicillin-Sulbactam			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Preparation H Cream			C				Not Reported
	Tocilizumab			C				Not Reported
	Vancomycin			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934411	DIRECT	Y	DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Refusal Of Treatment By Patient; Refusal Of Treatment By Relative	Remdesivir			S				Not Reported
	Ceflriaxone			C				Not Reported
	Doxycycli Ne			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934416	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934422	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934450	DIRECT	Y	OT			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934468	DIRECT	Y	DE			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Sars-Cov-2 Test Positive	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2020	17934475	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardio-Respiratory Arrest; Haemodynamic Instability; Pulseless Electrical Activity	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Hydroxychloroquine 400 Mg Po			C				Not Reported
	Azithromycin 500 Mg Iv X 1			C				Not Reported
	Azithromycin 250 Mg Po Once Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Methyprednisolone 40 Mg Iv Q12hr			C				Not Reported
	Thiamine 100 Mg Po Bid			C				Not Reported
	Zinc Sulfate 220 Mg Po Once Daily			C				Not Reported
	Vasopressin Iv 20 Units/Ml			C				Not Reported
	Enoxaparin 70 Mg Sq Q12hr			C				Not Reported
	Enoxaparin 70 Mg Sq Once Daily			C				Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
	Cefepime 1 Gm Iv			C				Not Reported
	Ascorbic Acid 1500 Mg Iv Q6hr			C				Not Reported
	Ascorbic Acid 1500 Po Once Daily			C				Not Reported
	Atorvastatin 80 Mg Po Once Daily			C				Not Reported
	Amiodarone 450 Mg Iv Infusion			C				Not Reported
	Amiodarone 200 Mg Po Once Daily			C				Not Reported
	Aspirin 81 Mg Po Once Daily			C				Not Reported
	B-12 1000 Mcg Sq Once Daily			C				Not Reported
	Diltiazem 100 Mg Iv Infusion			C				Not Reported
	Diltiazem 30 Mg Po Q8hr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17848032	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468530		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bilirubin Conjugated Increased; Transaminases Increased	Remdesivir			S	Unknown	Unk		Gilead
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Regular Hm			C				Not Reported
	Ketamine			C				Not Reported
	Lorazepam			C				Not Reported
	Norepinephrine			C				Not Reported
	Oxycodone			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol 3350			C				Not Reported
	Propofol			C				Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17873054	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470425		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Cardiac Arrest; Hypoxia; Respiratory Failure; Vomiting	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17881349	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470063		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Bisacodyl			C		Unk		Not Reported
	Chlorhexidine			C	Oral	Unk, Bid		Not Reported
	Robitussin Dm			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Menthol [Levomenthol]			C		Unk		Not Reported
	Methocarbamol			C		Unk		Not Reported
	Bengay [Menthol;Methyl Salicylate]			C		Unk		Not Reported
	Solu-Medrol			C		Unk		Not Reported
	Bactroban [Mupirocin]			C		Unk		Not Reported
	Zofran [Ondansetron]			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Miralax			C		Unk		Not Reported
	Ns			C		Unk		Not Reported
	Gabapentin			C				Not Reported
	Doxycycline			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

						Potassium Chloride	C	Unk		Not Reported
						Convalescent Plasma	C	Unk		Not Reported
						Cymbalta	C			Not Reported
						Neurontin	C			Not Reported
						Robaxin	C			Not Reported
						Lasix [Furosemide]	C			Not Reported
						Eliquis	C			Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
24-Jun-2020	17890267	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470430		50 YR	Female	USA	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Device Connection Issue; Drug Monitoring Procedure Incorrectly Performed	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead		
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
24-Jun-2020	17892602	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470906		74 YR	Male	USA	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Blood Creatinine Increased; Mouth Haemorrhage; Respiratory Failure; Urine Output Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead		
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead		
	Remdesivir			S				Gilead		
	Plasma			C		Unk		Not Reported		
	Tocilizumab			C		Unk		Not Reported		
	Heparin			C				Not Reported		
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
24-Jun-2020	17914726	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473031		54 YR	Male	USA	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		

Acute Kidney Injury; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Disseminated Intravascular Coagulation; Shock	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir	S				Gilead
	Succinylcholine Bromide	C				Not Reported
	Fentanyl	C				Not Reported
	Norepinephrine	C				Not Reported
	Cisatracurium	C				Not Reported
	Propofol	C				Not Reported
	Ketamine	C				Not Reported
	Azithromycin	C				Not Reported
	Ceftriaxone	C				Not Reported
	Epoprostenol	C				Not Reported
	Famotidine	C				Not Reported
	Heparin	C				Not Reported
	Insulin Lispro	C				Not Reported
	Vancomycin	C				Not Reported
	Insulin Regular Hm	C				Not Reported
	Midazolam	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17932085	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472177			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Chills; Dyspnoea; Hypertension; Oxygen Saturation Decreased; Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17935081	DIRECT	Y	HO			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Guaifenesin			C				Not Reported
	Heparin			C				Not Reported

		Hydrocodone-Chlorpheniramine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17935114	DIRECT	Y				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered	Remdesivir Injection			S	Intravenous drip		30 MIN	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17935120	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Das181			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936231	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Respiratory Failure	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936237	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)		9 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936244	DIRECT	Y				48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Calcium Gluconate			C				Not Reported
	Chlorhexidine Topical			C				Not Reported
	Dextrose D50w			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Metoprolol			C				Not Reported
	Ocular Lubricant (Artificial Tears)			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Veletri			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936250	DIRECT	Y	HO			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir 100 Mg/20ml	Y		S	Intravenous drip			Gilead
	Cefepime 1000 Mg			C				Not Reported
	Linezolid 600 Mg			C				Not Reported
	Dexamethasone 20 Mg			C				Not Reported
	Tocilizumab 600 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936256	DIRECT	Y				88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

Aminotransferase Increased	Vancomycin			C						Not Reported
	Piperacillin/Tazobactam			C						Not Reported
	Fentanyl			C						Not Reported
	Dexamethasone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17936262	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Increased; Haemodialysis; Respiratory Failure	Remdesivir	Y		S	Intravenous bolus		8 DAY	Gilead
	Atracurium			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Lispro			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Senna-Docusate			C				Not Reported
	Hydromorphone			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17938926	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472220		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Hypotension; Supraventricular Extrasystoles; Ventricular Tachycardia	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17940295	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0474225		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Remdesivir			S	Unknown	Unk			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17940954	DIRECT	Y	OT			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Solution For Injection	Y		S	Intravenous bolus			Gilead
	Amlodipine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Heparin			C				Not Reported
	Insulin Isophane			C				Not Reported
	Insulin Lispro			C				Not Reported
	Latanoprost			C				Not Reported
	Metronidazole			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Polyethylene Glycol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17940981	DIRECT	Y	DE			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17940998	DIRECT	Y	DE			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypoxia; Respiratory Acidosis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

			Ascorbic Acid		C				Not Reported
			Dexamethasone		C				Not Reported
			Atorvastatin		C				Not Reported
			Propofol		C				Not Reported
			Cholecalciferol		C				Not Reported
			Cisatracurium		C				Not Reported
			Etomidate		C				Not Reported
			Fentanyl		C				Not Reported
			Ferrous Gluconate		C				Not Reported
			Heparin		C				Not Reported
			Insulin Glargine		C				Not Reported
			Insulin Lispro		C				Not Reported
			Insulin Regular		C				Not Reported
			Magnesium Sulfate		C				Not Reported
			Midazolam		C				Not Reported
			Zinc Sulfate		C				Not Reported
			Pantoprazole		C				Not Reported
			Pregabalin		C				Not Reported
			Rocuronium		C				Not Reported
			Sodium Bicarbonate		C				Not Reported
			Vitamin A		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941007	DIRECT	Y				25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Therapeutic Environment	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Cafazolin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Methadone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941017	DIRECT	Y	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspnoea; Platelet Count Increased	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead
	Acetaminophen 325mg Po Q6h Pain 1-3, Fever	C				Not Reported
	Benzonatate 100-200mg Po Q8h	C				Not Reported
	Enoxaparin 30mg Subq Q12h	C				Not Reported
	Ketorolac 15mg Iv Q6h Prn Pain 4-6	C				Not Reported
	Melatonin 6mg Po Qhs Prn	C				Not Reported
	Methylprednisolone 30mg Iv Q8h	C				Not Reported
	Methylprednisolone 30mg Iv Q12h	C				Not Reported
	Promethazine-Codeine 6.25 /10/5ml Po Q4h Prn	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941055	DIRECT		OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941061	DIRECT	Y	OT			24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tociluzumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941070	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
	Doxycycline			C					Not Reported
	Amlopine			C					Not Reported
	Carvedilol			C					Not Reported
	Tamsulosin			C					Not Reported
	Aspirin			C					Not Reported
	Enoxaparin			C					Not Reported
	Methylprednisolone			C					Not Reported
	Prednisone			C					Not Reported
	Atorvastatin			C					Not Reported
	Quetiapine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941080	DIRECT	Y	LT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Oxygen Saturation Decreased	Remdesivir			S	Intravenous bolus			Gilead
	Buspirone			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941088	DIRECT	Y	DE, LT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Blood Creatinine Increased; Glomerular Filtration Rate Increased; Hypotension; Hypoxia; Right Ventricular Failure	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead
	Acetaminophen 325mg Pr Q4h			C				Not Reported
	Albumin 25g Iv Q6h			C				Not Reported
	Azithromycin 500mg Iv Q24h			C				Not Reported
	Senokot-S 8.6/50mg 2 Tabs Qhs			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Cisatracurium 10mg Iv Q1h Prn Vent Synchrony			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Epinephrine Infusion			C				Not Reported
	Epoprostenol Continuous Neb			C				Not Reported

			Fentanyl Infusion			C				Not Reported
			Folic Acid 1mg Ng Daily			C				Not Reported
			Heparin 5000 Units Subq Q8h			C				Not Reported
			Duoneb Q4h			C				Not Reported
			Linezolid 600mg Iv Q12h			C				Not Reported
			Midazolam Infusion			C				Not Reported
			Mvi With Minerals			C				Not Reported
			Norepinephrine Infusion			C				Not Reported
			Pantoprazole 40mg Iv Q24h			C				Not Reported
			Phenylephrine Infusion			C				Not Reported
			Pip/Tazo			C				Not Reported
			Propofol Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941097	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19; Fibrin D Dimer Increased; Hypercalcaemia; Hypoxia; Leukocytosis; Pneumonia; Renal Failure; Tachycardia; Tachypnoea	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead
	Albumin 12.5-25 Grams Iv			C				Not Reported
	Aspirin Ec 81mg Daily			C				Not Reported
	Atorvastatin 40mg Qhs			C				Not Reported
	Azithromycin 500mg Iv Q24h			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Carvedilol 6.25mg Po Bid			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Precedex Infusion			C				Not Reported
	Enoxaparin 40mg Daily			C				Not Reported
	Famotidine 20mg Iv Q12h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Insulin Lispro Sliding Scale 4x/Day			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Nicardipine Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Amiodarone Infusion			C				Not Reported
	Amiodarone 200mg Po Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941108	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead
	Acetaminophen 650mg Po Q6h Pain 1-3, Fever			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Po Daily			C				Not Reported
	Enoxaparin 40mg Qhs And 30mg Bid			C				Not Reported
	Robitussin Dm 5ml Po Q4h Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941115	DIRECT	Y	HO			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Nephropathy Toxic; Renal Impairment	Remdesivir Injection 100mg/20ml (5mg/Ml)	Y		S	Intravenous drip	Other Frequency:Once;	1 DAY	Unknown
	Tocilizumab Injections	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Not Reported
	Mucomyst 20%			C				Not Reported
	Maalox Plus			C				Not Reported
	Abscorbic Acid 500mg Tablet			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Atorvastatin 40mg Tablet			C				Not Reported
	Chlorhexidine Oral Rinse			C				Not Reported
	Dexamethasone 5mg Iv			C				Not Reported
	Enoxparin 35mg Sq			C				Not Reported
	Etomidate 16mg Iv			C				Not Reported
	Famotidine 20mg Iv			C				Not Reported
	Melatonin 10mg Po			C				Not Reported
	Zosyn 3.75mg Iv			C				Not Reported
	Rocuronium 70mg Iv			C				Not Reported
	Vancomycin 1250mg Iv			C				Not Reported

		Zinc 220mg			C					Not Reported
		Tocilizumab Injections			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941156	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alanine Aminotransferase Increased; Hypoxia; Oxygen Saturation Decreased; Pneumonia; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead
	Acetaminophen 325mg Po Q6h Prn Pain 1-3			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv/Po Daily			C				Not Reported
	Precedex Infusion			C				Not Reported
	Diltiazem Infusion			C				Not Reported
	Enoxaparin 30mg Q12h Or 40mg Q24h			C				Not Reported
	Famotidine 20mg Iv Q12h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Furosemide			C				Not Reported
	Hydralazine 20mg Iv Q4h Prn			C				Not Reported
	Lantus Qhs			C				Not Reported
	Insulin Lispro Sliding Scale 4x/D			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Pip/Tazo			C				Not Reported
	Propofol Infusion			C				Not Reported
	Tocilizumab 400mg Iv Once			C				Not Reported
	Vecuronium 10mg Iv Q1h Prn Vent Dyssynchrony			C				Not Reported
	Vit C 1500mg Q6h, B1 200mg Iv Q12h			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941256	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypotension; Oxygen Saturation Decreased; Pulse Absent	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead
	Acetaminophen 650mg Po Q4h Prn Pain 1-3, Fever	C				Not Reported
	Aspirin Ec 81mg Daily	C				Not Reported
	Atorvastatin 20mg Qhs	C				Not Reported
	Azithromycin 500mg Iv Q24h	C				Not Reported
	Cefepime 1g Iv Q6h	C				Not Reported
	Ceftriaxone 1g Iv Q24h	C				Not Reported
	Dexamethasone 6mg Po Daily	C				Not Reported
	Precedex Infusion	C				Not Reported
	Enoxaparin 40mg Subq Daily	C				Not Reported
	Epinephrine Infusion	C				Not Reported
	Epoprostenol Continuous Neb	C				Not Reported
	Famotidine 20mg Iv Q12h	C				Not Reported
	Lantus 25-30 Units Qhs	C				Not Reported
	Insulin Lispro Sliding Scale 4x/D	C				Not Reported
	Metoclopramide 10mg + Diphenhydramine 25mg Iv Q6h	C				Not Reported
	Metoprolol 5mg Iv Q4h Prn Sbp > 160 Or Hr>100	C				Not Reported
	Tocilizumab 400mg Iv Once	C				Not Reported
	Vitamin C 1g Q12h, Zinc 2250mg Po Q12h	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941265	DIRECT	Y	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Hypotension	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941275	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941286	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:200 Once,100x4days;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2020	17941803	DIRECT	Y	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir 100mg			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17818496	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0468321		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Acute Respiratory Distress Syndrome; Covid-19 Pneumonia; Hypernatraemia; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin [Enoxaparin Sodium]			C		100 Mg		Not Reported
	Insulin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Levophed			C		Unk		Not Reported
	Dopamine			C		Unk		Not Reported
	Epinephrine Hydrochloride			C		Unk		Not Reported

	Phenylephrine	C		Unk	Not Reported
	Epoprostenol	C		Unk	Not Reported
	Vancomycin	C		Unk	Not Reported
	Piperacillin/Tazobactam	C		Unk	Not Reported
	Heparin	C		Unk	Not Reported
	Amiodarone	C		Unk	Not Reported
	Ketamine [Ketamine Hydrochloride]	C		Unk	Not Reported
	Morphine	C		Unk	Not Reported
	Rocuronium	C		Unk	Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	800 Mg	Not Reported
	Sodium Bicarbonate	C		Unk	Not Reported
	Vasopressin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17881950	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470915		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Alprazolam			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Vitamin E [Tocopherol]			C		Unk		Not Reported
	Ondansetron			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Proscar			C		Unk		Not Reported
	Zestril			C		Unk		Not Reported
	Tamsulosin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17882692	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469672		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17892599	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470904		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cerebrovascular Accident; Depressed Level Of Consciousness; Hemiparesis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S				Gilead
	Plasma			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17923215	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473789		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Dextromethorphan			C				Not Reported
	Enoxaparin			C				Not Reported
	Gabapentin			C				Not Reported
	Acetaminophen			C				Not Reported
	Lactulose			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Compazine [Prochlorperazine Maleate]			C				Not Reported

	Cisatracurium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17925226	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473427		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Death; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Epoprostenol			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Lantus			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levothyroxine			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Propofol			C				Not Reported
	Sodium Bicarbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17940248	EXPEDITED (15-DAY)		LT, OT	US-SA-2020SA158391			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Cytokine Storm; Disseminated Intravascular Coagulation; Haemoglobin Decreased; Hyperglycaemia; Hyperkalaemia; Hypotension; Iron Deficiency; Lactic	Lovenox			S	Subcutaneous	80 Mg		Sanofi
	Remdesivir			S	Unknown	Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Duloxetine			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported

Acidosis; Liver Injury; Pneumonia; Retroperitoneal Haematoma; Septic Shock; Shock Haemorrhagic; Swelling	Midazolam	C	Unk	Not Reported
	Levetiracetam	C	Unk	Not Reported
	Pantoprazole	C	Unk	Not Reported
	Propofol	C	Unk	Not Reported
	Otezla	C	Unk	Not Reported
	Tocilizumab	C	Unk	Not Reported
	Vancomycin	C	Unk	Not Reported
	Furosemide	C	Unk	Not Reported
	Ceftriaxone	C	Unk	Not Reported
	Ferrous Sulfate	C	Unk	Not Reported
	Methylprednisolone	C	Unk	Not Reported
	Polyethylene Glycol [Macrogol]	C	Unk	Not Reported
	Cefepime	C	Unk	Not Reported
	Ativan	C	Unk	Not Reported
	Docusate;Senna	C	Unk	Not Reported
	Lactulose	C	Unk	Not Reported
	Nicotine	C	Unk	Not Reported
	Duoneb	C	Unk	Not Reported
	Suboxone	C	Unk	Not Reported
	Chlorhexidine	C	Unk	Not Reported
	Azithromycin	C	Unk	Not Reported
	Acetaminophen	C	Unk	Not Reported
	Dextromethorphan	C	Unk	Not Reported
	Meropenem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942646	DIRECT	Y	OT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir			S	Intravenous (not			Not Reported

Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Therapy Cessation	otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942947	DIRECT	Y	OT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Liver Function Test Increased; Therapy Cessation	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942953	DIRECT	Y	OT			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dyspnoea; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus	Other Frequency:One Time;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942965	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir Injection	Y		S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942969	DIRECT	Y	LT, OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disease Progression; Hepatic Function Abnormal; Hypotension; Multiple Organ Dysfunction Syndrome; Renal Impairment; Tachycardia	Remdesivir	S	Intravenous (not otherwise specified)		Gilead
	Acetaminophen	C			Not Reported
	Albuterol	C			Not Reported
	Amiodarone	C			Not Reported
	Aspirin	C			Not Reported
	Atorvastatin	C			Not Reported
	Azithromycin	C			Not Reported
	Docusate Sodium	C			Not Reported
	Ephinephrine	C			Not Reported
	Famotidine	C			Not Reported
	Fentanyl	C			Not Reported
	Furosemide	C			Not Reported
	Guaifenesin	C			Not Reported
	Heparin	C			Not Reported
	Humulin N	C			Not Reported
	Humulin R	C			Not Reported
	Atrovent Hfa	C			Not Reported
	Lactulose	C			Not Reported
	Melatonin	C			Not Reported
	Meropenem	C			Not Reported
	Methylprednisolone	C			Not Reported
	Midazolam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17942976	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Rash Erythematous; Rash Papular; Tachycardia	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Not Reported
	Azithromycin 250 Mg			C				Not Reported
	Effexor 150 Mg			C				Not Reported
	Mirtazapine 45 Mg			C				Not Reported
	Ceftriaxone 2g			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17943053	DIRECT	Y	HO			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intestinal Perforation	Remdesivir		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Genentech
	Ceftriaxone		C				Not Reported
	Azithromycin		C				Not Reported
	Methylprednisolone		C				Not Reported
	Enoxaparin		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17946669	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475647		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	200 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17946844	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475654		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	200 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17946943	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475655		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	200 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17947072	DIRECT	Y	DE			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Respiratory Rate Increased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17947079	DIRECT	Y	OT			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin 40 Mg			C				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported
	Cholecalciferol 4000 Iu			C				Not Reported
	Dexamethasone 5 Mg Iv			C				Not Reported
	Folic Acid 1 Mg			C				Not Reported
	Furosemide 40 Mg Iv Once			C				Not Reported
	Pantoprazole 40 Mg Iv			C				Not Reported
	Piperacillin-Tazobactam 2.25 G Iv			C				Not Reported
	Selenium 200 Mcg			C				Not Reported
	Thiamine 250 Mg			C				Not Reported
	Vitamin E 1000 Iu			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Dexmedetomidine Infusion 400 Mc/ 100 Ml			C				Not Reported
	Heparin Infusion 25000 Units/ 500 Ml			C				Not Reported
	Norepinephrine Infusion 16 Mg/ 250 Ml			C				Not Reported
	Ascorbic Acid 1000 Mg			C				Not Reported
	Aspirin 81 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17947091	DIRECT	Y	OT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ceftriaxone	C				Not Reported
	Amiodarone	C				Not Reported
	Apixaban	C				Not Reported
	Dexamethasone	C				Not Reported
	Azithromycin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17947136	DIRECT	Y	OT			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutrophil Count Decreased; Platelet Count Decreased; White Blood Cell Count Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin			C				Not Reported
	Carvedilol			C				Not Reported
	Citalopram			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Diltiazem			C				Not Reported
	Doxycycline			C				Not Reported
	Insulin Glargine			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Pantoprazole			C				Not Reported
	Warfarin			C				Not Reported
	Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17947147	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17947154	DIRECT	Y	DE			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Gilead
	Amiodarone 150 Mg Iv			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 80 Mg			C				Not Reported
	Cefepime 2 Gm Iv			C				Not Reported
	Dexamethasone 10 Mg Iv			C				Not Reported
	Famotidine 20 Mg Iv			C				Not Reported
	Fluconazole 200 Mg Iv			C				Not Reported
	Metronidazole 500 Mg Iv			C				Not Reported
	Valproic Acid 500 Mg Iv			C				Not Reported
	Vancomycin 1000 Mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17947164	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dialysis; Renal Failure	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2020	17948215	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17835873	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468468		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg		Not Reported

	Amlodipine	C	Oral	10 Mg		Not Reported
	Apixaban	C	Oral	2.5 Mg		Not Reported
	Doxazosin	C	Oral	4 Mg		Not Reported
	Hydralazine	C		Unk		Not Reported
	Lorazepam	C		Unk		Not Reported
	Combivent Respimat	C		Unk		Not Reported
	Ascorbic Acid	C	Oral	500 Mg		Not Reported
	Cholecalciferol	C	Oral	2000 Iu		Not Reported
	Levothyroxine	C		Unk		Not Reported
	Zinc Sulfate	C		Unk		Not Reported
	Tylenol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17835882	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468290		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Swelling; Throat Irritation	Remdesivir			S	Unknown	200 Mg		Gilead
	Albuterol Hfa			C		Unk		Not Reported
	Nystatin			C		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported
	Vitamin D [Colecalciferol]			C		Unk		Not Reported
	Vitamin C [Ascorbic Acid]			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Dipridamole			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Letrozole			C		Unk		Not Reported

	Amlodipine	C		Unk	Not Reported
	Lisinopril	C		Unk	Not Reported
	Sitagliptin	C		Unk	Not Reported
	Metformin	C		Unk	Not Reported
	Empagliflozin	C		Unk	Not Reported
	Diphenhydramine	C	Intravenous (not otherwise specified)	Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17877950	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0470603		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Docusate;Senna			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17892305	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469665		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C	Oral	20 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	30 Mg		Not Reported
	Etomidate			C	Intravenous (not otherwise specified)	20 Mg		Not Reported

	Famotidine	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	400 Mg	Not Reported
	Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Midazolam	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	2500 Mg	Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948303	DIRECT	Y	LT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Gilead
	Albuterol Mdi Q6hr Prn			C				Not Reported
	Guaifenesin 600 Mg Q12h			C				Not Reported
	Allopurinol 300 Mg Bid			C				Not Reported
	Aspirin 81 Mg Qd			C				Not Reported
	Enoxaparin 40 Mg Qhs			C				Not Reported
	Humalog Ssi			C				Not Reported
	Levothyroxine 137mcg Qd			C				Not Reported
	Omeprazole 20 Qd			C				Not Reported
	Melatonin 5mg Qhs			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948310	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rash; Rash Erythematous; Red Man Syndrome	Remdesivir	S	Intravenous bolus	Other Frequency:Once;		Gilead
	0.9% Sodium Chloride 1l	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17948403	DIRECT	Y	HO			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949179	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475738		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Albumin (Human)			C				Not Reported
	Azithromycin			C				Not Reported
	Senokot-S			C				Not Reported
	Ceftriaxone Sodium			C				Not Reported
	Cisatracurium			C				Not Reported
	Enoxaparin			C				Not Reported
	Epinephrine			C				Not Reported
	Epoprostenol [Epoprostenol Sodium]			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Heparin			C				Not Reported
	Duoneb			C				Not Reported
	Linezolid			C				Not Reported
	Midazolam			C				Not Reported

		Multivitamins;Minerals			C					Not Reported
		Norepinephrine			C					Not Reported
		Pantoprazole			C					Not Reported
		Phenylephrine			C					Not Reported
		Piperacillin & Tazobactam			C					Not Reported
		Propofol			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949182	DIRECT	Y				37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Labetalol			C				Not Reported
	Furosemide			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949291	DIRECT	Y	HO, OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Right; Heart Rate Decreased; Nodal Rhythm; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Azithromycin 500mg Po Qam			C				Not Reported
	Ondansetron 4mg Iv X1 At 2052 On 6/20			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949624	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Atorvastatin			C				Not Reported
	Amlodipine			C				Not Reported
	Fioricet			C				Not Reported
	Enoxaparin			C				Not Reported
	Zetia			C				Not Reported
	Robitussin			C				Not Reported
	Mag-Ox 400			C				Not Reported
	Niacin Cr			C				Not Reported
	Zinc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949632	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agonal Rhythm; Gastrointestinal Haemorrhage; Hypotension; Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17949709	DIRECT	Y	DS			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Hemiparesis	Remdesivir			S	Intravenous bolus			Gilead
	Heparin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950233	DIRECT	Y	DE			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip			Gilead

		Tocilizumab			C					Not Reported
		Hydrocortisone			C					Not Reported
		Dexamethasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950264	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Hypotension; Respiratory Distress	Remdesivir			S	Intravenous bolus			Gilead
	Tocilizumab			C				Not Reported
	Levofloxacin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950269	DIRECT	Y	LT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Rhabdomyolysis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950326	DIRECT	Y	OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17950382	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Pyrexia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17951358	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0475730		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Ceftriaxone			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Asa			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Guaifenesin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952105	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475740		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Aspirin Ec			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported

	Cefepime	C	Not Reported
	Ceftriaxone	C	Not Reported
	Dexamethasone	C	Not Reported
	Precedex	C	Not Reported
	Enoxaparin	C	Not Reported
	Epinephrine	C	Not Reported
	Epoprostenol	C	Not Reported
	Famotidine	C	Not Reported
	Lantus	C	Not Reported
	Insulin Lispro	C	Not Reported
	Metoclopramide	C	Not Reported
	Metoprolol	C	Not Reported
	Tocilizumab	C	Not Reported
	Vitamin C [Ascorbic Acid]	C	Not Reported
	Normal Saline	C	Not Reported
	Clopidogrel	C	Not Reported
	Dicyclomine [Dicycloverine Hydrochloride]	C	Not Reported
	Insulin	C	Not Reported
	Metformin	C	Not Reported
	Metoprolol Tartrate	C	Not Reported
	Ranitidine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952320	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476715		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952476	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476711		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952547	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0476372		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Increased; Product Dose Omission Issue	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Ketorolac			C				Not Reported
	Melatonin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Promethazine - Codeine [Codeine Phosphate; Promethazine Hydrochloride]			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952601	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475755		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C				Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Once		Not Reported
	Azithromycin			C	Oral	250 Mg, Qd		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Thiamine			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported

	Vasopressin	C		Unk		Not Reported
	Enoxaparin	C	Subcutaneous	70 Mg, Bid		Not Reported
	Enoxaparin	C	Subcutaneous	70 Mg, Qd		Not Reported
	Cefepime	C		Unk		Not Reported
	Ascorbic Acid	C	Intravenous (not otherwise specified)	1500 Mg, Q6h		Not Reported
	Ascorbic Acid	C	Oral	1500 Mg, Qd		Not Reported
	Atorvastatin	C	Oral	80 Mg, Qd		Not Reported
	Amiodarone	C	Intravenous (not otherwise specified)	450 Mg		Not Reported
	Amiodarone	C	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952608	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476714		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown			Gilead
	Remdesivir			S		Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952610	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0476284		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin Fumarate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Precedex			C				Not Reported
	Diltiazem			C				Not Reported
	Enoxaparin			C				Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Hydralazine			C				Not Reported
	Lantus			C				Not Reported
	Insulin Lispro Dci			C				Not Reported
	Norepinephrine Bitartrate			C				Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Propofol			C				Not Reported
	Vecuronium			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Zinc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952624	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0476289		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Carvedilol			C				Not Reported
	Dexamethasone			C				Not Reported
	Precedex			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Lispro			C				Not Reported
	Midazolam			C				Not Reported
	Nicardipine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Amiodarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952666	EXPEDITED (15-DAY)			US-GILEAD-2020-0476262		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17952676	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476716		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17955105	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17955109	DIRECT	Y	DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Arrest; Pancytopenia; Pulseless Electrical Activity; Sepsis	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17955112	DIRECT	Y	DE			91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Remdesivir	S	Intravenous (not otherwise specified)			Gilead
	Levofloxacin	C				Not Reported
	Azithromycin	C				Not Reported
	Ceftriaxone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17955114	DIRECT	Y				45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Heart Rate Decreased; Sinus Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17955116	DIRECT	Y	DE			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Bradycardia; Cardiac Arrest; Condition Aggravated; Pulseless Electrical Activity; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17955124	DIRECT	Y				33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Transcription Medication Error	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Ketorolac			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17955127	DIRECT	Y				59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Daily;	1 DAY	Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17955136	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased	Remdesivir	Y		S	Intravenous drip			Gilead
	Odefsey			C				Not Reported
	Lisinopril			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Atorvastatin			C				Not Reported
	Asa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2020	17955138	DIRECT	Y	DS			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis; Pneumatosis Intestinalis; Respiratory Failure	Remdesivir	Y		S	Intravenous bolus		4 DAY	Gilead
	Famotidine 20 Mg Iv Qd			C				Not Reported
	Morphine 2mg Iv Prn Q2h			C				Not Reported
	Dexamethasone 6mg Iv Qd			C				Not Reported
	Ondansetron 4mg Iv Prn Q8hr			C				Not Reported
	Morphine Drip 0.025mg/Hour			C				Not Reported
	Dexmedetomidine Iv Drip			C				Not Reported
	Insulin Drip			C				Not Reported
	Metronidazole 500mg Iv Q 8 Hrs			C				Not Reported

		Cefepime 2g Iv Q 12h			C					Not Reported
		Lorazepam 2mg Q4hprn			C					Not Reported
		Enoxaparin 40mg Sq			C					Not Reported
		Melatonin 3mg Hs			C					Not Reported
		Azithromycin Oral			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17955143	DIRECT	Y	LT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hypotension; Ischaemic Hepatitis; Transaminases Increased	Remdesivir			S	Intravenous drip			Gilead
	Centrum Multivitamin Oral Solution			C				Not Reported
	Enoxaparin 40 Mg Injection			C				Not Reported
	Phytonadione 5 Mg Tablet			C				Not Reported
	Potassium Phosphate 30 Mmol Injection			C				Not Reported
	Acetaminophen 650 Mg Oral Liquid			C				Not Reported
	Cefepime 2g Injection			C				Not Reported
	Dexmedetomidine Continuous Infusion			C				Not Reported
	Famotidine 20 Mg Injection			C				Not Reported
	Fentanyl Continuous Infusion			C				Not Reported
	Hydrocortisone 50 Mg Injection			C				Not Reported
	Insulin Aspart			C				Not Reported
	Peptamen Continuous Enteral Nutrition			C				Not Reported
	Polyethylene Glycol 17g Packet			C				Not Reported
	Senna Oral Solution			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2020	17955146	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			C				Not Reported

	Ceftriaxone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17955074	DIRECT		OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased; Therapy Change	Warfarin			S				Not Reported
	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17955085	DIRECT	Y	OT			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Infusion Related Reaction; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17955147	DIRECT	Y				76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; General Physical Health Deterioration	Remdesivir	Y		S	Intravenous bolus		2 DAY	Gilead
	Amiodarone			C				Not Reported
	Atracurium			C				Not Reported
	Buspirone			C				Not Reported
	Docusate			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Memantine			C				Not Reported
	Metoprolol			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Pregabalin			C				Not Reported
	Senna			C				Not Reported
	Venlafaxine			C				Not Reported
	Epoprostenol			C				Not Reported

Hydromorphone	C		Not Reported
Midazolam	C		Not Reported
Norepinephrine	C		Not Reported
Propofol	C		Not Reported
Sodium Bicarbonate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17955173	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17955174	DIRECT	Y	DE			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17955178	DIRECT	Y	LT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Ammonia Increased; Aspartate Aminotransferase Increased; International Normalised Ratio Increased; Prothrombin Time Prolonged; Sars-Cov-2 Test Positive	Remdesivir Lyophilized Powder			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir Lyophilized Powder			S	Intravenous bolus			Gilead
	Amiodarone Continuous Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17955182	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2020	17955186	DIRECT	Y	OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Sinus Bradycardia	Remdesivir			S	Intravenous drip			Gilead
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17818878	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-GILEAD-2020-0468569		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S				Gilead
	Acetaminophen			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Potassium Bicarbonate			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17835865	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468246		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Abnormal; Aspartate Aminotransferase Abnormal; Hepatic Enzyme Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Atorvastatin	C	Oral	20 Mg		Not Reported
	Propofol	C		Unk		Not Reported
	Chlorhexidine	C	Oral	15 Ml, Bid		Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	10 Mg, Qd		Not Reported
	Enoxaparin	C	Subcutaneous	70 Mg, Bid		Not Reported
	Famotidine	C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Insulin Aspart	C	Subcutaneous	Unk		Not Reported
	Insulin Detemir	C	Subcutaneous	10 Units		Not Reported
	Piperacillin/Tazobactam	C	Intravenous (not otherwise specified)	3.375 G, Tid		Not Reported
	Acetaminophen	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17848037	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468536		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17882776	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469674		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not	100 Unk		Gilead

						otherwise specified)				
		Enoxaparin			C		Unk			Not Reported
		Famotidine			C		Unk			Not Reported
		Lorazepam			C		Unk			Not Reported
		Hydromorphone			C		Unk			Not Reported
		Metoclopramide			C		Unk			Not Reported
		Ceftriaxone			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17955177	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1059286		64 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Hypersensitivity; Off Label Use; Rash Maculo-Papular	Piperacillin/Tazobactam			S	Intravenous drip	13 Gram, Qd		Not Reported
	Remdesivir			S	Intravenous drip	100 Milligram, Qd		Mylan
	Hydroxychloroquine Sulfate			C	Oral	400 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956863	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Covid-19 Pneumonia; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone 2 Gm Ivpb Daily			C				Not Reported
	Dexamethasone 6 Mg Ivp Daily			C				Not Reported
	Doxycycline 100 Mg Po Twice Daily			C				Not Reported
	Enoxaparin 70 Mg Sq Twice Daily			C				Not Reported
	Iohexol (Omnipaque) 90 Ml Iv X 1			C				Not Reported
	Multivitamin With Minerals Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956864	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956865	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir			S	Intravenous drip			Gilead
	Cefepime			C				Not Reported
	Amiodarone			C				Not Reported
	Doxycycline			C				Not Reported
	Fentanyl			C				Not Reported
	Vecuronium			C				Not Reported
	Propofol			C				Not Reported
	Levophed			C				Not Reported
	Levothyroxine			C				Not Reported
	Decadron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956866	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Disease Progression; Liver Function Test Increased; Therapy Interrupted	Remdesivir			S				Not Reported
	Fenofibrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956881	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		4 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956968	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Wrong Technique In Product Usage Process	Remdesivir	Y		S	Intravenous drip			Gilead
	Ofirmev Iv			C				Not Reported
	Acetaminophen Sol 325mg/10ml			C				Not Reported
	Acetylcysteine Sol 20%			C				Not Reported
	Albuterol Inh			C				Not Reported
	Amiodarone Iv			C				Not Reported
	Atorvastatin 10mg			C				Not Reported
	Benzonatate 100mg			C				Not Reported
	Calcium Gluconate Iv			C				Not Reported
	Ceftriaxone 1g			C				Not Reported
	Dexamethasone 6mg Iv			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Epinephrine Drip			C				Not Reported
	Famotidine 20mg Iv			C				Not Reported
	Insulin Glargine			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Zosyn			C				Not Reported
	Propofol			C				Not Reported
	Vancomycin			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956974	DIRECT	Y	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Abnormal	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956980	DIRECT	Y	OT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Fentanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956985	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Ascorbic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Tramadol			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956992	DIRECT	Y				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956994	DIRECT	Y				32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Product Use Issue	Remdesivir	S	Intravenous (not otherwise specified)		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17956998	DIRECT	Y				33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957001	DIRECT	Y				34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957034	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Covid-19; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir			S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Tocilizumab 600mg Iv X1			C				Not Reported
	Diprivan 1000 Mg/100 Ml Infusion			C				Not Reported
	Norepinephrine 16mg/250 Ml Infusion			C				Not Reported
	Sodium Bicarbonate 150 Meq/ 1000 Ml Swi			C				Not Reported
	Vasopressin 40 Unit/100 Ml Ns			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957040	DIRECT	Y				27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957735	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476718		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Glomerular Filtration Rate Decreased	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957740	EXPEDITED (15-DAY)			US-GILEAD-2020-0476394		25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			C		Unk		Not Reported
	Cefazolin			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Methadone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17957773	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476697		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Remdesivir	S	Unknown		Gilead
	Remdesivir	S	Unknown		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17958217	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0476315		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin [Enoxaparin Sodium]			C				Not Reported
	Robitussin Dm			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17960773	DIRECT	Y	OT			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S				Not Reported
	Benzocain-Menthol Lozenge			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17960783	DIRECT	Y	DE			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Condition Aggravated; Metabolic Acidosis	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17960861	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Dispensing Error; Product Preparation Error	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17960869	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Inadequately Controlled; Blood Pressure Systolic Increased; Hypertension	Remdesivir			S	Intravenous bolus		5 DAY	Gilead
	Amlodipine			C				Not Reported
	Azithromycin			C				Not Reported
	Carvedilol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cefuroxime			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Humalog			C				Not Reported
	Ultimate Flora Probiotic			C				Not Reported
	Lisinopril			C				Not Reported
	Potassium Chloride			C				Not Reported
	Pravastatin			C				Not Reported
	Acetaminophen			C				Not Reported
	Haldol			C				Not Reported
	Hydralazine			C				Not Reported
	Effer-K (Potassium Bicarb - Citric Acid)			C				Not Reported
	Magnesium Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17960883	DIRECT	Y	HO			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue; Transcription Medication Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17960897	DIRECT	Y				24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17960951	DIRECT	Y	HO			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Peripheral Swelling; Swelling Face	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Azithromycin			C				Not Reported
	Cefdinir			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961055	DIRECT	Y				50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

	Tocilizumab			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961069	DIRECT	Y	HO			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardio-Respiratory Arrest; Heart Rate Decreased; Hepatic Enzyme Increased; Ischaemic Hepatitis; Pulseless Electrical Activity; Renal Tubular Necrosis	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961119	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Hepatic Enzyme Increased; Renal Impairment; Therapy Cessation	Remdesivir			S	Intravenous bolus			Not Reported
	Albuterol/Ipratropium Nebulizer Q6h			C				Not Reported
	Ascorbic Acid 500mg Po Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 2g Iv Daily			C				Not Reported
	Cholecalciferol 1000 Unit Po Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Docusate/Senna 50-8.6mg 2 Tab Po Qhs			C				Not Reported
	Heparin 5000 Unit Q8h			C				Not Reported
	Insulin Glargine 30 Unit Subq Qhs			C				Not Reported
	Insulin Lispro Sliding Scale Subq Q4h			C				Not Reported
	Pantoprazole 40mg Iv Daily			C				Not Reported
	Zinc 220mg Po Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961135	DIRECT	Y	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Maternal Exposure During Pregnancy; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961246	DIRECT	Y				36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961537	DIRECT	Y	DE			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bacteraemia; General Physical Health Deterioration; Hepatic Failure; Hypernatraemia; Multiple Organ Dysfunction Syndrome; Septic Shock; Toxic Encephalopathy; Unresponsive To Stimuli	Remdesivir 100mg Vial			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg Vial			S	Intravenous (not otherwise specified)	Other Frequency:9 Doses;		Gilead
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Pantoprazole			C				Not Reported
	Vancomycin			C				Not Reported
	Furosemide			C				Not Reported
	Insulin			C				Not Reported
	Fentanyle			C				Not Reported

		Norepinephrine			C						Not Reported
		Propofol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17835876	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0468482		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Blood Alkaline Phosphatase Increased; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Atorvastatin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Desvenlafaxine			C		Unk		Not Reported
	Epoetin Alfa			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Hydrocortisone Sodium Succinate			C		Unk		Not Reported
	Hydrocortisone Sodium Succinate			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Methadone			C		Unk		Not Reported
	Methadone			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Pregabalin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Q4hr		Not Reported
	Nystatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17886471	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0471777		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Pleuritic Pain	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Cholecalciferol			C		2000 Iu, Qd		Not Reported
	Melatonin			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Humalog			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17910399	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472995		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased	Remdesivir			S	Unknown	Unk		Gilead
	Epinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17914699	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0473311		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Bile Output Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported

Albuterol [Salbutamol]	C	Unk	Not Reported
Amiodarone	C	Unk	Not Reported
Amlodipine	C	Unk	Not Reported
Ampicillin And Sulbactam	C	Unk	Not Reported
Apixaban	C	Unk	Not Reported
Atenolol	C	Unk	Not Reported
Atorvastatin	C	Unk	Not Reported
Calcium Gluconate	C	Unk	Not Reported
Chlorhexidine Gluconate	C	Unk	Not Reported
Cholecalciferol	C	Unk	Not Reported
Dexmedetomidine	C	Unk	Not Reported
Dextrose	C	Unk	Not Reported
Digoxin	C	Unk	Not Reported
Etomidate	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Glucagon	C	Unk	Not Reported
Glycopyrrolate [Glycopyrronium Bromide]	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Insulin Lispro	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17914716	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0472817		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Pneumonia; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Norepinephrine Bitartrate			C				Not Reported

	Convalescent Plasma			C	Intravenous (not otherwise specified)	2 Units			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17962822	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemodynamic Instability; Heart Rate Decreased; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen Iv			C				Not Reported
	Albumin 25%			C				Not Reported
	Albuterol 0.5% Hhn Prn			C				Not Reported
	Carbidopa-Levodopa 25/100			C				Not Reported
	Dopamine Infusion			C				Not Reported
	Enoxaparin 95 Mg			C				Not Reported
	Haloperidol 2.5 Mg Prn			C				Not Reported
	Insulin Aspart Prn			C				Not Reported
	Ipratroprium/Albuterol Hhn			C				Not Reported
	Lorazepam 2 Mg X 1			C				Not Reported
	Morphine 2 Mg Prn			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Pantoprazole 40 Mg Iv			C				Not Reported
	Pimavanserin 17 Mg			C				Not Reported
	Sennosides-Docusate 1 Tab			C				Not Reported
	Vasopressin Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17962874	DIRECT	Y	HO			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen 1000 Mg			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Clopidogrel 75 Mg			C				Not Reported
	Dextromethorphan-Guaifenesin			C				Not Reported

	30-600 Mg			
	Dexmedetomidine Infusion	C		Not Reported
	Dopamine Infusion	C		Not Reported
	Enoxaprin 40 Mg	C		Not Reported
	Tocilizumab 400 Mg X 1	C		Not Reported
	Furosemide 20-40 Mg	C		Not Reported
	Haloperidol 1-2.5 Mg Prn	C		Not Reported
	Levothyroxine 50 Mcg	C		Not Reported
	Linezolid 600 Mg Iv	C		Not Reported
	Melatonin 3-9 Mg	C		Not Reported
	Methylprednisolone/Prednisone	C		Not Reported
	Norepinephrine Infusion	C		Not Reported
	Olanzapine 2.5 Mg	C		Not Reported
	Pantoprazole 40 Mg	C		Not Reported
	Piperacillin-Tazobactam 4.5 G	C		Not Reported
	Quetiapine 12.5 Mg	C		Not Reported
	Rivastigmine 9.5 Mg Td	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17962879	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Jaundice	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500 Mg			C				Not Reported
	Ceftriaxone 2 G			C				Not Reported
	Heparin Infusion			C				Not Reported
	Methylprednisolone 40 Mg			C				Not Reported
	Chlorthalidone 25 Mg			C				Not Reported
	Mometasone-Formoterol Inh			C				Not Reported
	Guaifenesin-Codeine Prn			C				Not Reported
	Acetaminophen Prn			C				Not Reported
	Labetalol Iv Prn			C				Not Reported
	Dexmedetomidine Infusion			C				Not Reported
	Verapamil 360 Mg			C				Not Reported
	B Complex W/ Zinc			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Propofol Infusion			C				Not Reported
	Fentanyl Ivp Prn			C				Not Reported
	Cisatracurium Infusion			C				Not Reported

		Nicardipine Infusion			C					Not Reported
		Chlordiazepoxide 100 Mg			C					Not Reported
		Dexamethasone			C					Not Reported
		Sennosides			C					Not Reported
		Pantoprazole/Famotidine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17962885	DIRECT	Y				84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Remdesivir			S		Other Frequency:Once;		Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17962891	DIRECT	Y	OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Remdesivir	Y		S	Intravenous drip			Gilead
	Fosphenytoin			C				Not Reported
	Levetiracetam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17962898	DIRECT	Y	OT			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir 100 Mg Iv Daily In Ns 250 Ml	Y		S	Intravenous drip			Gilead
	Albuterol Hfa 180 Mcg Q6 Hrs			C				Not Reported
	Ascorbate 500 Mg Po Q6 Hrs			C				Not Reported
	Cholecalciferol 2000 Iu Oral Daily			C				Not Reported
	Enoxaparin 60 Mg Sq Daily			C				Not Reported
	Famotidine 20 Mg Po Bid			C				Not Reported
	Flonase 50 Mcg Inhaled Daily			C				Not Reported
	Insulin Sq			C				Not Reported

		Loratidine 10 Mg Po Daily		C					Not Reported
		Melatonin 6 Mg Po Qhs		C					Not Reported
		Oxymetolazone Q Spary Nasal Qid		C					Not Reported
		Zinc Sulfate 220 Mg Po Daily		C					Not Reported
		Promethazine With Codeine 5 Ml Po Q6 Hrs Prn Cough		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17963068	DIRECT	Y	OT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17963540	DIRECT	Y	OT			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17963546	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous drip	Other Frequency:X1, 100 Mg Q24h;		Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17963622	DIRECT	Y	OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500 Mg Po Bid With Food			C				Not Reported
	Benonate 200 Mg 2 Caps Po Q8h Prn For Cough			C				Not Reported
	Cholecalciferol 2,000 Iu Po Daily With Food			C				Not Reported
	Enoxaparin 80 Mg Sq Q12h			C				Not Reported
	Methylprednisolone 20 Mg Iv Q6h			C				Not Reported
	Pantoprazole 40 Mg Po Daily			C				Not Reported
	Zinc Sulfate 200 Mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17963628	DIRECT	Y				33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatine Phosphokinase Increased	Remdesivir Lyophilized Powder			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17963633	DIRECT	Y				72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17964680	EXPEDITED (15-DAY)			US-GILEAD-2020-0477205			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose	Remdesivir			S	Unknown	Unk		Gilead
	Remdesivir			S	Unknown	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17967202	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17967203	DIRECT	Y	OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulmonary Hypertension; Right Ventricular Enlargement; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500 Mg Po Four Times Daily			C				Not Reported
	Cholcecalciferol 4,000 Iu Po Daily			C				Not Reported
	Digoxin 0.25 Mg Iv Q8h X3 Doses			C				Not Reported
	Enoxaparin 40 Mg Sq Q12h			C				Not Reported
	Ferrous Sulfate 325 Mg Po Daily			C				Not Reported
	Gabapentin 600 Mg Po Qhs			C				Not Reported
	Hydrochlorothiazide 12.5 Mg Po Daily			C				Not Reported
	Furosemide 20 Mg Iv Bid			C				Not Reported
	Levothyroxine 75 Mcg Po Daily			C				Not Reported
	Lisinopril 20 Mg Po Daily			C				Not Reported

		Methylprednisolone 20 Mg Iv Q6h			C					Not Reported
		Multivitamin 1 Tab Po Daily			C					Not Reported
		Ometa-3 Fatty Acids 1 Gram Po Daily			C					Not Reported
		Pantoprazole 40 Mg Po Daily			C					Not Reported
		Ramelteon 8 Mg Po Qhs			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17967229	DIRECT	Y				51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500 Mg Po Bid			C				Not Reported
	Azithromycin 500 Mg Iv Q24h			C				Not Reported
	Ceftriaxone 1 Gm Iv Q24h			C				Not Reported
	Enoxaparin 50 Mg Sq Q12h			C				Not Reported
	Famotidine 20 Mg Po Q12h			C				Not Reported
	Guaifenesin 200 Mg Po Q8h			C				Not Reported
	Methylprednisolone 40 Mg Iv Q12h			C				Not Reported
	Ramelteon 8 Mg Po Qhs			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17967232	DIRECT	Y				87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time Only;		Gilead
	Ascorbic Acid 1,000 Mg Po Daily With Food			C				Not Reported
	Calcium/Vitamin D 500mg/200 Iu Po Bid			C				Not Reported
	Cholecalciferol 2,000 Iu Po Daily			C				Not Reported
	Docusate 200 Mg Po Bid			C				Not Reported
	Enoxaparin 30 Mg Sq Q12h			C				Not Reported

Famotidine 20 Mg Iv Q24h	C		Not Reported
Guaifenesin 600 Mg Er Po Bid	C		Not Reported
Methylprednisolone 40 Mg Iv Q12h	C		Not Reported
Zinc Sulfate 220 Mg Po Daily	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17967235	DIRECT	Y	OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17967239	DIRECT	Y				80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Increased; Renal Impairment; Sinus Bradycardia	Remdesivir	Y		S	Intravenous bolus			Gilead
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2020	17967243	DIRECT	Y	HO			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17862152	EXPEDITED (15-DAY)			US-GILEAD-2020-0468845		334 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Product Administered To Patient Of Inappropriate Age	Remdesivir		S	Intravenous (not otherwise specified)	37.5 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17902698	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0472649		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Allopurinol			C				Not Reported
	Apixaban			C				Not Reported
	Atorvastatin			C				Not Reported
	Coreg			C				Not Reported
	Enoxaparin			C				Not Reported
	Duloxetine			C				Not Reported
	Ertapenem			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Furosemide			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Insulin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Phenylephrine			C				Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17908558	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0472776		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Propofol	C				Not Reported
	Famotidine	C				Not Reported
	Insulin Regular [Insulin Bovine]	C				Not Reported
	Normal Saline	C				Not Reported
	Azithromycin	C				Not Reported
	Ceftriaxone	C				Not Reported
	Fentanyl	C				Not Reported
	Midazolam	C				Not Reported
	Acetaminophen	C				Not Reported
	Ascorbic Acid	C				Not Reported
	Enoxaparin	C				Not Reported
	Insulin Detemir	C				Not Reported
	Methylprednisolone	C				Not Reported
	Thiamine	C				Not Reported
	Zinc Sulfate	C				Not Reported
	Duoneb	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17909732	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0472780		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Colchicine			S	Oral	0.6 Mg		Not Reported
	Ascorbic Acid			C				Not Reported
	Cisatracurium			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Potassium Chloride			C				Not Reported
	Propofol			C				Not Reported
	Tocilizumab			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported

		Atorvastatin			C					Not Reported
		Chlorhexidine			C					Not Reported
		Cholecalciferol			C					Not Reported
		Famotidine			C					Not Reported
		Insulin Aspart			C					Not Reported
		Levemir			C					Not Reported
		Methylprednisolone			C					Not Reported
		Sitagliptin			C					Not Reported
		Zinc Sulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17967464	DIRECT	Y	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Selinexor Study Drug			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968112	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Transaminases Increased	Remdesivir			S	Intravenous bolus			Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Bio-K Plus			C				Not Reported
	Insulin Lispro			C				Not Reported
	Famotidine			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Lorazepam			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968116	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip			Gilead
	Normal Saline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968121	DIRECT	Y	OT			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous drip		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968349	DIRECT	Y	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968402	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Pravastatin 40 Mg-Home Medication			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968586	DIRECT	Y				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Interrupted	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17968698	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Glomerular Filtration Rate Decreased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amlodipine 5mg(Home Med)			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Rocephin 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Lovenox 100mg Every 12 Hours			C				Not Reported
	Lantus 5-10 Units			C				Not Reported
	Protonix 40mg Iv Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17969275	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0476702		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970016	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0475372		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Liver Function Test Increased; Multiple Organ Dysfunction Syndrome; Renal Impairment; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Alprazolam			C		Unk, Prn		Not Reported
	Guaifenesin			C		Unk, Prn		Not Reported
	Acetaminophen;Hydrocodone			C		Prn		Not Reported
	Vecuronium			C		Unk, Prn		Not Reported

	Ascorbic Acid	C		Unk	Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Azithromycin	C	Oral	Unk	Not Reported
	Calcium Gluconate	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Dopamine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Etomidate	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Finasteride	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Fondaparinux	C		Unk	Not Reported
	Normal Saline	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Hydrocortisone Sodium Succinate	C		Unk	Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Phenylephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Phentolamine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970047	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477761		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970432	EXPEDITED (15-DAY)			US-GILEAD-2020-0477650		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17970835	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477744		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17971155	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477738		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Guaifenesin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17971172	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477689		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17971828	EXPEDITED (15-DAY)			US-GILEAD-2020-0477767		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17971883	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477750			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17972596	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17972654	DIRECT	Y	HO			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Hyperhidrosis; Infusion Related Reaction; Tachycardia; Tachypnoea	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;	60 MIN	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17972661	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; International Normalised Ratio Increased; Prothrombin Time Prolonged	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2020	17972667	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17878097	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470902		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Pantoprazole			C		Unk		Not Reported

	Piperacillin / Tazobactam	C	Unk		Not Reported
	Vancomycin	C	Unk		Not Reported
	Midazolam	C	Unk		Not Reported
	Angiotensin Ii	C	Unk		Not Reported
	Diltiazem	C	Unk		Not Reported
	Ketamine	C	Unk		Not Reported
	Coumadin	C			Not Reported
	Levophed	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17882667	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470043		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Oxybutin			C		Unk		Not Reported
	Losartan			C				Not Reported
	Enoxaparin			C				Not Reported
	Potassium			C				Not Reported
	Gabapentin			C				Not Reported
	Duloxetine			C				Not Reported
	Lorazepam			C				Not Reported
	Rocuronium			C				Not Reported
	Melatonin			C				Not Reported
	Levothyroxine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Buspirone			C				Not Reported
	Amlodipine			C				Not Reported
	Prednisone			C				Not Reported
	Propofol			C				Not Reported
	Pencillin			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17887632	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470690		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Ischaemic Hepatitis; Liver Function Test Increased; Shock; Supraventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Amiodarone			S	Unknown			Not Reported
	Aripiprazole			C		Unk		Not Reported
	Aripiprazole			C				Not Reported
	Famotidine			C		Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Insulin Regular Hm			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Potassium			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Bupropion			C		Unk		Not Reported
	Bupropion			C				Not Reported
	Cetrizine			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Sertraline			C		Unk		Not Reported
	Sertraline			C				Not Reported
	Trazodone			C		Unk		Not Reported
	Ocrelizumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17892597	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470641		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Propofol			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Insulin Regular Hm			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Linezolid			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Metolazone			C		Unk		Not Reported
	Insulin Isophane			C		Unk		Not Reported
	Bumetanide			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17918275	EXPEDITED (15-DAY)			US-GILEAD-2020-0472228		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Lactobacillus Rhamnosus			C				Not Reported
	Methylprednisolone Sodium Succinate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17940380	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0474255		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Throat Tightness	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			S	Unknown	Unk		Not Reported
	Doxycycline			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Dextroamphetamine Sulfate			C		Unk		Not Reported
	Citalopram			C		Unk		Not Reported
	Clonazepam			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Amitriptyline			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973626	DIRECT	Y	HO, RI			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dialysis; Renal Impairment; Respiratory Distress; Therapy Interrupted	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973938	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Oedematous Pancreatitis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Fenofibrate			C				Not Reported
	Acetaminophen			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Diltiazem			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Ketorolac			C				Not Reported
	Hydromorphone			C				Not Reported
	Levothyroxine			C				Not Reported
	Metoprolol			C				Not Reported
	Ondansetron			C				Not Reported
	Oxycodone Immediate Release			C				Not Reported
	Oxycodone 12 Hour			C				Not Reported
	Pantoprazole			C				Not Reported
	Simethicone			C				Not Reported
	Prochlorperazine			C				Not Reported
	Ropinirole			C				Not Reported
	Ramelteon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973951	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Remdesivir	S	Intravenous drip		Gilead
	Dexamethasone	C			Not Reported
	Heparin	C			Not Reported
	Insulin	C			Not Reported
	Levetiracetam	C			Not Reported
	Pantoprazole	C			Not Reported
	Piperacelli/Tazobactam	C			Not Reported
	Propofol	C			Not Reported
	Valproic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973957	DIRECT	Y				37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973971	DIRECT		OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen 500mg Po Q6h Prn			C				Not Reported
	Dexamethasone 6mg Ivp Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973976	DIRECT		OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin 81mg Daily			C				Not Reported

		Dexamethasone 6mg Ivp Daily			C					Not Reported
		Norepinephrine Iv Drip			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17973979	DIRECT		HO			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974146	DIRECT	Y				80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974168	DIRECT	Y	HO, OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Neo-Synephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974184	DIRECT	Y				77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir	S	Intravenous (not otherwise specified)			Not Reported
	Lipitor	C				Not Reported
	Rocephin	C				Not Reported
	Zithromax	C				Not Reported
	Aspirin	C				Not Reported
	Allopurinol	C				Not Reported
	Tylenol	C				Not Reported
	Lovenox	C				Not Reported
	Solumedrol	C				Not Reported
	Mucinex	C				Not Reported
	Prilosec	C				Not Reported
	Verapamil	C				Not Reported
	Lantus	C				Not Reported
	Humalog	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974353	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Dexamethasone 6 Mg Daily			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Enoxaparin 40 Mg Daily			C				Not Reported
	Acetaminophen 650 Mg Every 4 Hours As Needed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974358	DIRECT	Y	LT, OT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Cisatracurium			C				Not Reported

	Dexamethasone	C	Not Reported
	Fentanyl	C	Not Reported
	Heparin	C	Not Reported
	Hydralazine	C	Not Reported
	Humulin R	C	Not Reported
	Reglan	C	Not Reported
	Versed	C	Not Reported
	Norepinephrine	C	Not Reported
	Protonix	C	Not Reported
	Propofol	C	Not Reported
	Senna	C	Not Reported
	Robitussin Dm	C	Not Reported
	Vancomycin	C	Not Reported
	Ceftazidime	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974408	EXPEDITED (15-DAY)			US-GILEAD-2020-0478162		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974504	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Cardiac Arrest; Glomerular Filtration Rate Decreased; International Normalised Ratio Increased; Liver Function Test Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17974863	EXPEDITED (15-DAY)			US-GILEAD-2020-0478240			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17976027	EXPEDITED (15-DAY)			US-GILEAD-2020-0478186			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17976305	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478153			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17982134	DIRECT	Y				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17982135	DIRECT	Y	HO			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chronic Kidney Disease	Remdesivir	Y	S	Intravenous bolus		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17982136	DIRECT	Y	DE			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir	Y		S				Gilead
	Cefepime			C				Not Reported
	Dexmedotomidine			C				Not Reported
	Docusate			C				Not Reported
	Epinephrine			C				Not Reported
	Hydromorphone			C				Not Reported
	Methylprednisolone			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Sennoside			C				Not Reported
	Sucralfate			C				Not Reported
	Vancomycin			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17982137	DIRECT		HO			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir	Y		S				Gilead
	Alprazolam			C				Not Reported
	Anakinra			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Metoprolol			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17982138	DIRECT	Y				81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Hot; Flushing	Remdesivir			S				Not Reported
	Morphine Inj			C				Not Reported
	Lantus			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Norepinephrine			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17982146	DIRECT	Y				48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17982150	DIRECT	Y	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiac Arrest; Hypoxia; Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17982155	DIRECT	Y	DE			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Arrest;	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

Hypercapnia; Hypoxia; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome	Convalescent Plasma			C					Not Reported
	Enoxaparin 60 Mg Sq Q12hrs			C					Not Reported
	Methylprednislone 60 Mg Ivp Q6hr			C					Not Reported
	Remdesivir 200 Mg Iv X 1			C					Not Reported
	Remdesivir 100 Mg Iv Once Daily			C					Not Reported
	Zinc 220 Mg Po Bid			C					Not Reported
	Ascorbic Acid 1,000 Mg			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2020	17982267	DIRECT	Y	DS, LT, OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Arrest; Hepatitis; Pulseless Electrical Activity	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17877919	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470907		91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Amlodipine			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Metoprolol			C				Not Reported
	Diltiazem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17878098	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470903		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19; Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17887631	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470900		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Arformoterol			C				Not Reported
	Budesonide			C				Not Reported
	Docusate;Senna			C				Not Reported
	Duloxetine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Rocuronium			C				Not Reported
	Ropinirole			C				Not Reported
	Lorazepam			C				Not Reported
	Fentanyl			C				Not Reported
	Ketamine			C				Not Reported
	Midazolam			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17898305	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0471872		91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Death	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Amiodarone			C		Unk		Not Reported
	Apixaban			C		Unk		Not Reported
	Plasma			C		Unk		Not Reported
	Bumex			C		Unk		Not Reported
	Plavix			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Protonix [Omeprazole]			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Nitroglycerin			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Isosorbide Mononitrate			C		Unk		Not Reported
	Tamsulosin			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported
	Bicarbonate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17898779	EXPEDITED (15-DAY)		DE, DS, LT, OT	US-GILEAD-2020-0472460		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter;	Remdesivir			S	Intravenous (not	200 Mg, Qd		Gilead

Cerebrovascular Accident; Death; Pulmonary Function Test Decreased			otherwise specified)		
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Plasma	C		Unk	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Amiodarone	C		Unk	Not Reported
	Vancomycin	C		Unk	Not Reported
	Zosyn	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported
	Lovenox [Enoxaparin Sodium]	C		40 Mg Sq Bid	Not Reported
	Lovenox [Enoxaparin Sodium]	C		80 Mg Sq Bid	Not Reported
	Lovenox [Enoxaparin Sodium]	C		40 Mg Sq Bid	Not Reported
	Acetaminophen	C			Not Reported
	Albuterol [Salbutamol]	C			Not Reported
	Aspirin [Acetylsalicylic Acid]	C			Not Reported
	Enoxaparin	C			Not Reported
	Normal Saline	C			Not Reported
	Piperacillin/Tazobactam	C			Not Reported
	Potassium Chloride	C			Not Reported
	Albuterol;Ipratropium	C			Not Reported
	Famotidine	C			Not Reported
	Fentanyl	C			Not Reported
	Furosemide	C			Not Reported
	Propofol	C			Not Reported
	Succinylcholine [Suxamethonium Chloride]	C			Not Reported
	Folic Acid	C			Not Reported
	Lactated Ringers	C			Not Reported
	Thiamine	C			Not Reported
	Vecuronium	C			Not Reported
	Formoterol	C			Not Reported
	Iohexol	C			Not Reported
	Potassium Phosphate [Potassium Phosphate Dibasic]	C			Not Reported
	Sodium Bicarbonate	C			Not Reported
	Lorazepam	C			Not Reported
	Morphine	C			Not Reported

	Scopolamine [Hyoscine]			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17918232	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473912		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amlodipine			C				Not Reported
	Cholecalciferol			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Levothyroxine			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982159	DIRECT	Y				16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982172	DIRECT	Y				24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982173	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiac Arrest	Remdesivir			S				Not Reported
	Norepinephrine			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982174	DIRECT	Y				35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982175	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dialysis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982177	DIRECT	Y	HO			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Amiodarone Drip			C				Not Reported
	Ascorbic Acid Tablet			C				Not Reported

		Cholecalciferol			C					Not Reported
		Zinc Sulfate Capsule			C					Not Reported
		Azithromycin Iv			C					Not Reported
		Ceftriaxone Iv			C					Not Reported
		Fentanyl Drip			C					Not Reported
		Midazolam Drip			C					Not Reported
		Dexamethasone Iv			C					Not Reported
		Enoxaparin Inj			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982178	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982179	DIRECT	Y				34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Product Dose Omission Issue; Transcription Medication Error	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982180	DIRECT	Y	DE			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Condition Aggravated; Hepatic Failure; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982188	DIRECT	Y	DS, OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Ticagrelor			C				Not Reported
	Eptifibatide			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Phenylephrine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982194	DIRECT	Y	DE			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus			Gilead
	Enoxaparin 90mg			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levofloxacin 750mg			C				Not Reported
	Lorazepam 0.5mg			C				Not Reported
	Acetaminophen 650mg			C				Not Reported
	Dopamine Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982200	DIRECT	Y	LT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury	Remdesivir	Y	S	Intravenous bolus	Gilead
	Albuterol 4mg		C		Not Reported
	Cefepime 1g		C		Not Reported
	Chlorhexidine Mouthwash		C		Not Reported
	Dexamethasone 6mg		C		Not Reported
	Enoxaparin 90mg		C		Not Reported
	Furosemide 20mg		C		Not Reported
	Insulin Lispro		C		Not Reported
	Linezolid 600mg		C		Not Reported
	Meropenem 1g		C		Not Reported
	Multivitamin		C		Not Reported
	Cisatracurium Drip		C		Not Reported
	Fentanyl Drip		C		Not Reported
	Norepinephrine Drip		C		Not Reported
	Propofol Drip		C		Not Reported
	Midazolam Drip		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982201	DIRECT	Y	LT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Dialysis; General Physical Health Deterioration; Klebsiella Infection; Liver Function Test Increased; Pneumonia Bacterial; Sepsis	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Amiodarone			C				Not Reported
	Docusate Senna			C				Not Reported
	Famotidine			C				Not Reported
	Insulin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported
	Senna			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Phenylephrine			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982207	DIRECT	Y	LT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Urea Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous bolus			Gilead
	Albuterol 4mg			C				Not Reported
	Amlodipine 10mg			C				Not Reported
	Ceftriaxone 1g			C				Not Reported
	Cholrhexidine Mouthwash			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Enoxaparin 100mg			C				Not Reported
	Furosemide 40mg			C				Not Reported
	Guaifenesin 400mg			C				Not Reported
	Pantoprazole 40mg			C				Not Reported
	Miralax 17g			C				Not Reported
	Sertraline 100mg			C				Not Reported
	Vancomycin 1500mg			C				Not Reported
	Potassium Chloride 20meq			C				Not Reported
	Precedex Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported
	Versed Drip			C				Not Reported
	Azithromycin 500mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2020	17982210	DIRECT	Y				16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17982208	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2020	17982259	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Cessation	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	17982241	DIRECT	Y	DE			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Concomitant Disease Aggravated; Covid-19	Remdesivir			S				Gilead
	Calcium Gluconate			C				Not Reported
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2020	17982246	DIRECT	Y	DS, HO, OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Haemodialysis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17892593	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0470929		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Zinc			C				Not Reported
	Pantoprazole			C				Not Reported
	Meropenem			C				Not Reported
	Levothyroxine			C				Not Reported
	Levetiracetam			C				Not Reported
	Hydrocortisone			C				Not Reported
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Cipro [Ciprofloxacin]			C				Not Reported
	Azithromycin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Dopamine			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported
	Plasma			C				Not Reported
	Nacl			C				Not Reported
	Alprazolam			C				Not Reported
	Calcium Gluconate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983088	DIRECT	Y	HO			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Creatinine Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983112	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Inflammation; Liver Injury	Remdesivir For Injection 100mg/Vial			S	Intravenous bolus			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983193	DIRECT		OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Erythema; Infusion Site Extravasation; Infusion Site Pain; Infusion Site Swelling; Lip Swelling; Swollen Tongue	Remdesivir (Emergency Use) 5mg/Ml Solution	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q24h;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983340	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir (Emergency Use) 5mg/Ml Solution	Y		S	Intravenous (not otherwise specified)	Frequency: Q24h		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983444	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir (Emergency Use) 5mg/Ml Solution	Y		S		Other Route:Iv		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983447	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir (Emergency Use) 5mg/Ml Solution	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q24h; Other Route:Iv		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983700	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir (Emergency Use) 5mg/Ml Solution	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q24h;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983885	EXPEDITED (15-DAY)			US-GILEAD-2020-0478621			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983929	DIRECT	Y				81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Remdesivir	Y		S	Intravenous bolus		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983955	DIRECT		HO, OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Oxygen Saturation Decreased; Renal Impairment	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17983959	DIRECT	Y	OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Famotidine			C				Not Reported
	Docusate			C				Not Reported
	Morphine			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984057	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984090	DIRECT	Y				40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Sars-Cov-1 Test Positive	Remdesivir			S	Intravenous drip			Gilead
	Budesonide 0.5 Mg Nebulizer			C				Not Reported
	Caboxymethylcellulose Ophthalmic Drops			C				Not Reported
	Cisatracurium			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Aspart & Detemir			C				Not Reported
	Lpratropium-Albuterol Nebulizer			C				Not Reported
	Ketamine			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984415	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Prerenal Failure; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984440	DIRECT	Y	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Lisinopril			C				Not Reported
	Montelukast			C				Not Reported
	Tamsulosin			C				Not Reported
	Vancomycin			C				Not Reported
	Sodium Chloride 0.9%			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984443	DIRECT	Y				70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cough; Dyspnoea; Pyrexia	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Carboxymethylcellulose Ophthalmic Drops			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported

		Fentanyl			C						Not Reported
		Hydralazine			C						Not Reported
		Insulin			C						Not Reported
		Propofol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17984445	DIRECT	Y	OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip	Other Frequency:One Time Dose;		Gilead
	Acetaminophen			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Ondansetron			C				Not Reported
	Ergocalciferol			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17985429	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479043		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa			C				Not Reported
	Ascorbate De Sodium			C				Not Reported
	Cholecalciferol			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Flonase [Fluticasone Propionate]			C				Not Reported
	Insulin			C				Not Reported
	Loratadine			C				Not Reported
	Melatonin			C				Not Reported
	Oxymetazoline			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Promethazine With Codeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17987868	DIRECT	Y				47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swelling; Thrombotic Thrombocytopenic Purpura	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17987887	DIRECT	Y	OT			14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Remdesivir			S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Anakinra			C				Not Reported
	Clindamycin			C				Not Reported
	Cefepime			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Bactrim			C				Not Reported
	Advair			C				Not Reported
	Montelukast			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17987893	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Brain Death; Brain Herniation; Cerebral Infarction; Cerebrovascular Accident; Pupil Fixed; Renal Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S				Gilead
	Atovastatin			C				Not Reported
	Cefepime			C				Not Reported
	Cholecalciferol			C				Not Reported
	Clopidogrel			C				Not Reported

	Asprin	C	Not Reported
	Ascorbic Acid	C	Not Reported
	Amlodipine	C	Not Reported
	Dexamethasone	C	Not Reported
	Docusate	C	Not Reported
	Heparin	C	Not Reported
	Humalog	C	Not Reported
	Lantus	C	Not Reported
	Vancomycin	C	Not Reported
	Zinc	C	Not Reported
	Fentany Drip	C	Not Reported
	Versed Drip	C	Not Reported
	Nicardipine Drip	C	Not Reported
	Norepinephrine Drip	C	Not Reported
	Rucuronium Drip	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17987900	DIRECT	Y	OT			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Gilead
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ampicillin			C				Not Reported
	Dexamethasone			C				Not Reported
	Furosemide			C				Not Reported
	Sertraline			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17987905	DIRECT	Y	DE			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemodynamic Instability; Haemoglobin Decreased; Klebsiella Infection; Multiple Organ Dysfunction Syndrome;	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

Pneumonia Pseudomonal; Respiratory Failure; Thrombocytopenia	Albuterol	C	Not Reported
	Ascobic Acid	C	Not Reported
	Cholecalciferol	C	Not Reported
	Fentany	C	Not Reported
	Humalog	C	Not Reported
	Meropenem	C	Not Reported
	Methylperdnisolone Tapper Dose	C	Not Reported
	Micafungin	C	Not Reported
	Tocizilumab	C	Not Reported
	Protonix	C	Not Reported
	Selenium	C	Not Reported
	Zinc	C	Not Reported
	Vancomycin	C	Not Reported
	Tpn	C	Not Reported
	Heparin Drip	C	Not Reported
	Levoped Drip	C	Not Reported
	Versed Drip	C	Not Reported
	Rocuronium Drip	C	Not Reported
	Vasopressin	C	Not Reported
	Fondaprinux	C	Not Reported
	Heparin Subcut	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17987929	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen 650mg Supp			C				Not Reported
	Azithromycin 500mg Iv			C				Not Reported
	Dexmedetomidine Drip			C				Not Reported
	Dexamethasone 6mg Iv			C				Not Reported
	D5 Ns @ 125ml/Hr			C				Not Reported
	Docusate 100mg			C				Not Reported
	Enoxaparin 60mg Every 24 Hours			C				Not Reported
	Fentanyl 0.35-05mcg/Kg			C				Not Reported
	Guaifenesin 400mg			C				Not Reported
	Lactobacillus			C				Not Reported
	Levofloxacin 750mg			C				Not Reported

		Lorazepam			C					Not Reported
		Norepinephrine 0.05-3mcg/Kg/Min			C					Not Reported
		Pantoprazole 40mg			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17987937	DIRECT	Y	HO			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17988013	DIRECT	Y	HO			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Fibrinogen Increased; Blood Lactate Dehydrogenase Increased; Blood Urea Increased; C-Reactive Protein Increased; Chest X-Ray Abnormal; Covid-19; Dyspnoea; Interleukin Level Increased; Parosmia; Platelet Count Decreased; Respiratory Failure; Sars-Cov-2 Test Positive; Taste Disorder	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17988060	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Blood Calcium Decreased; Blood Creatinine Increased; Blood Sodium Decreased; Blood Urea Increased; Cardiac Arrest; Covid-19 Pneumonia; Oxygen Saturation Decreased; Renal Tubular Necrosis; Respiratory Failure; Sars-Cov-2 Test Positive; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Every 24 Hour;		Not Reported
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Insulin Aspart			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17988148	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sars-Cov-2 Test Positive; Vaginal Haemorrhage	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17988186	DIRECT	Y	HO			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ammonia Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Chills; Cough;	Remdesivir			S				Not Reported

Dyspnoea; Hypotension; Myalgia; Nausea; Oxygen Saturation Decreased; Platelet Count Decreased; Pneumonia Viral; Pyrexia; Renal Failure; Urine Output Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17988189	DIRECT	Y	HO			16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir 100 Mg/20 Ml Iv Solution (Eua Suppl	Y		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab (Actemra) 800mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2020	17988409	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17910125	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473143		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Death; Hepatotoxicity; Hypotension; Infection; Ischaemic Hepatitis; Ischaemic Hepatitis; Liver Function Test Increased; Platelet Count Decreased;	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetylcysteine			C	Oral	Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported

Pneumonia; Renal Impairment; Septic Shock	Enoxaparin	C	Unk	Not Reported
	Fentanyl	C	Unk	Not Reported
	Insulin Lispro	C	Unk	Not Reported
	Levalbuterol [Levosalbutamol]	C	Unk	Not Reported
	Norepinephrine	C	Unk	Not Reported
	Pantoprazole	C	Unk	Not Reported
	Propofol	C	Unk	Not Reported
	Normal Saline	C	Unk	Not Reported
	Zinc Sulfate	C	Unk	Not Reported
	Zosyn	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988860	DIRECT	Y				73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		10 DAY	Gilead
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cisatracurium			C				Not Reported
	Decadron			C				Not Reported
	Digoxin			C				Not Reported
	Fentanyl			C				Not Reported
	Lasix			C				Not Reported
	Heparin			C				Not Reported
	Norepinephrine			C				Not Reported
	Diprivan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988990	DIRECT	Y	OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Calculus Bladder; Flank	Remdesivir			S				Not Reported

Pain; Haematuria

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17988996	DIRECT	Y				84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Respiratory Symptom	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin 40 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Aspirin Ec 81 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989008	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; White Blood Cell Count Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ammonium Lactate Topical 1 App Bid			C				Not Reported
	Clonazepam 0.5 Mg Po Bid			C				Not Reported
	Dexamethasone 6 Mg Po Daily			C				Not Reported
	Divalproex Sodium 125 Mg Ec Tablet Po Tid			C				Not Reported
	Levetiracetam 1000 Mg Po Hs			C				Not Reported
	Mirtazapine 15 Mg Dis Tablet Po Hs			C				Not Reported
	Lactulose 40 G Po Bid Prn			C				Not Reported
	Melatonin 15 Mg Po Hs			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989012	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

		Hydrocodone-Homatropine 5-1.5 mg		C					Not Reported
		Bactrim Ds		C					Not Reported
		Cephalexin 500mg		C					Not Reported
		Insulin Lispro 4 Units		C					Not Reported
		Insulin Glargine 6 Units		C					Not Reported
		Benzonatate 200mg		C					Not Reported
		Acetaminophen 650mg		C					Not Reported
		Enoxaparin 40mg		C					Not Reported
		Dexamethasone 6mg Iv		C					Not Reported
		Albuterol 2.5mg Inh		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989536	DIRECT	Y	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Anorectal Discomfort; Hypophagia; Nausea; Oral Candidiasis; Oral Discomfort; Oral Discomfort; Therapy Cessation; Tongue Discomfort	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin 10mg			C				Not Reported
	Diltiazem 240mg Cd			C				Not Reported
	Famotidine 20mg			C				Not Reported
	Flecainide 150mg			C				Not Reported
	Hydrochlorothiazide 12.5 Mg			C				Not Reported
	Metoprolol 25mg			C				Not Reported
	Nystatin 5ml Oral Suspension			C				Not Reported
	Omeprazole 40mg			C				Not Reported
	Potassium			C				Not Reported
	Prednisone 40mg			C				Not Reported
	Rivaroxaban 20mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989541	DIRECT	Y	DE			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Acute	Remdesivir			S	Intravenous bolus			Gilead

Respiratory Failure; Bradycardia; Cardiac Arrest; Chest Pain; Confusional State; Electrocardiogram Abnormal; Hypoxia; Metabolic Encephalopathy; Pneumonia Viral; Pulse Absent; Pulseless Electrical Activity; Troponin Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989579	DIRECT		OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Amiodarone 200mg Po Daily			C				Not Reported
	Aspirin 162mg Po Daily			C				Not Reported
	Dexamethasone 8mg Ivp Daily			C				Not Reported
	Dexmedetomidine Iv Drip			C				Not Reported
	Dexamethasone 6mg Ivp Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989582	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479372		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Rosuvastatin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Tocilizumab			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989584	DIRECT		OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin 40mg Sq Daily			C				Not Reported
	Aspirin 162mg Po Daily			C				Not Reported
	Dexamethasone 8mg Ivp Daily			C				Not Reported
	Dexmedetomidine Iv Drip			C				Not Reported
	Furosemide 40mg Ivp Bid			C				Not Reported
	Dexamethasone 6mg Ivp Daily			C				Not Reported
	Norepinephrine Iv Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989596	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479362		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Bio K Plus			C				Not Reported
	Insulin Lispro			C				Not Reported
	Famotidine			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Lorazepam			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17989615	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0479459		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Unknown	Unk		Gilead
	Alprazolam			C				Not Reported
	Anakinra			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Metoprolol			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17990947	EXPEDITED (15-DAY)			US-GILEAD-2020-0479511		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Dose Omission; Product Dispensing Error	Remdesivir			S	Unknown	200 Mg		Gilead
	Remdesivir			S	Unknown	200 Mg		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993587	DIRECT	Y	DE			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inflammatory Marker Increased; Pulseless Electrical Activity; Suspected Covid-19	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remedesivir			C				Not Reported
	Nimbex			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Dexamethasone			C				Not Reported
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993623	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous bolus			Gilead
	Ceftriaxone 1 Gm Iv			C				Not Reported
	Albuterol-Ipratropium 3 Ml			C				Not Reported
	Apixaban 2.5 Mg			C				Not Reported
	Azithromycin 500 Mg Tab			C				Not Reported
	Dexamethasone 6 Mg Tab			C				Not Reported
	Famotidine 20 Mg Iv			C				Not Reported
	Metoprolol 50 Mg Tab			C				Not Reported
	Fentanyl Iv			C				Not Reported
	Norepinephrine Iv			C				Not Reported
	Propofol Iv			C				Not Reported
	Vasopressin Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993627	DIRECT	Y	HO			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir	Y		S				Gilead
	Sulfasalazine			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxazosin			C				Not Reported
	Benazepril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993645	DIRECT	Y	HO, LT, OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury;	Remdesivir			S	Intravenous (not			Gilead

Dialysis; Hyperkalaemia

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993651	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993658	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir (Eua)			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Amlodipine (Norvasc) Tablet 2.5 Mg			C				Not Reported
	Ascorbic Acid (Vitamin C) (Vitamin C) Tablet 500 Mg			C				Not Reported
	Aspirin Tablet 325 Mg			C				Not Reported
	Atorvastatin (Lipitor) Tablet 80 Mg			C				Not Reported
	Ceftriaxone (Rocephin) 2 Gm In Dextrose 5 % 100 Ml Ivpb			C				Not Reported
	Azithromycin (Zithromax) 500 Mg In Dextrose 5 % In Water (D5w) 250 Ml			C				Not Reported
	Dexamethasone (Decadron) Tablet 6 Mg			C				Not Reported
	Enoxaparin (Lovenox) 40 Mg/0.4 Ml Injection 40 Mg			C				Not Reported
	Famotidine (Pepcid) 20 Mg In Sodium Chloride (Pf) 0.9 % Iv			C				Not Reported
	Guaifenesin (Mucinex) 12 Hr Tablet 600 Mg			C				Not Reported
	Mirtazapine (Remeron) Tablet 45 Mg			C				Not Reported
	Pramipexole (Mirapex) Tablet			C				Not Reported

	0.375 Mg								
	Tamsulosin (Flomax) 24 Hr Capsule 0.8 Mg		C						Not Reported
	Thiamine Mononitrate (Vit B1) Tablet 100 Mg		C						Not Reported
	Zinc Sulfate (Zincate) Capsule 220 Mg		C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993663	DIRECT	Y				51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993705	DIRECT	Y	RI, OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Gilead
	Ceftazidime 2 G (Fortaz/Tazicef)			C				Not Reported
	Albuterol 90 Meg/Actuation Hfa Mdi 4 Puff (Proair/Proventilnentolin)			C				Not Reported
	Pecid 20mg			C				Not Reported
	Fentanyl (Pf) In Ns 10 Mcg/Ml Iv Soln			C				Not Reported
	Haloperidol Lactate In] 2 Mg (Haldol) :			C				Not Reported
	Lorazepam In] 2 Mg (Ativan)			C				Not Reported
	Midazolam (Pf) In] 2 Mg (Versed)			C				Not Reported
	Norepinephrine In Ns 8 Mg/250 Ml (32 Mcg/Ml) Lv Premix			C				Not Reported
	Phenylephrine 200 Mg In			C				Not Reported

	Sodium Chloride 0.9% 250 Ml Iv Soln			
	Quetiapine Tab 25 Mg (Seroquel) :	C		Not Reported
	Vancomycin Per Protocol	C		Not Reported
	Venlafaxine Tab 75 Mg (Effexor)	C		Not Reported
	Azithromycin 500mg (Zithromax)	C		Not Reported
	Ceftriaxone Add Vial 2 G (Rocephin)	C		Not Reported
	Lasix 40mg	C		Not Reported
	Vecuronium Inj 7.5 Mg (Norcuron)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993808	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Enoxaparin 150 Mg			C				Not Reported
	Hydralazine			C				Not Reported
	Ceftriaxone 1 Gm			C				Not Reported
	Insulin Glargine			C				Not Reported
	Dexamethasone 10 Mg			C				Not Reported
	Heparin 5000			C				Not Reported
	Acetaminophen 650			C				Not Reported
	Insulin Lispro			C				Not Reported
	Albuterol			C				Not Reported
	Mometasone			C				Not Reported
	Ondansetron			C				Not Reported
	Aromatic Inhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2020	17993885	DIRECT	Y				75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Doxycycline			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17877952	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470593		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumothorax; Pseudomonal Bacteraemia	Blinded Placebo			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Blinded Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Blinded Tocilizumab			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ceftriaxone			C		Unk		Not Reported
	Doxycycline			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Ketamine			C		Unk		Not Reported
	Ativan			C				Not Reported
	Morphine			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17882304	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0470944		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Lactic Acid Increased; Bronchiectasis; Death; Emphysema; Fibrin D Dimer Increased; Inflammatory Marker Increased; Oxygen	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Convalescent Plasma			C		Unk		Not Reported
	Doxycycline			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

Consumption Increased; Pulmonary Embolism; Shock Symptom	Docusate Sodium	C	Unk	Not Reported
	Donepezil	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Fluoxetine	C	Unk	Not Reported
	Melatonin	C	Unk	Not Reported
	Omeprazole	C	Unk	Not Reported
	Potassium Chloride	C	Unk	Not Reported
	Propofol	C	Unk	Not Reported
	Risperidone	C	Unk	Not Reported
	Senna [Senna Alexandrina]	C	Unk	Not Reported
	Quetiapine	C	Unk	Not Reported
	Polyethylene Glycol [Macrogol]	C	Unk	Not Reported
	Fentanyl	C	Unk	Not Reported
	Heparin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17917676	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0473055		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Miralax			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Solu-Medrol			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17993892	DIRECT	Y	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994296	DIRECT	Y	LT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported
	Methylprednisilone			C				Not Reported
	Lisinopril/Hctz 20/25mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994533	DIRECT	Y	HO, OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Condition Aggravated; Sepsis; Therapy Interrupted	Remdesivir			S				Not Reported
	Methylprednisolone			C				Not Reported
	Furosemide			C				Not Reported
	Dexmedatomidine			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994568	DIRECT		DE			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S				Gilead
	Allopurinol			C				Not Reported
	Methotrxate			C				Not Reported
	Pravastatin			C				Not Reported
	Valsartan			C				Not Reported
	Nebumetone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994788	DIRECT	Y	LT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Disorientation; Dyspnoea; Tachycardia; Tachypnoea	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994791	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Hypotension; Hypoxia; Respiratory Disorder; Septic Shock; Tachycardia; Tachypnoea	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994796	DIRECT	Y	DE			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Aspartate Aminotransferase Increased; Atrial Fibrillation; Body Temperature Increased; Cardiac Arrest; Death; Hypercapnia; Hypoxia; Otorrhoea; Oxygen Saturation Decreased; Streptococcus Test Positive	Remdesivir			S	Intravenous drip			Gilead
	Diamox			C				Not Reported
	Human Albumin			C				Not Reported
	Cefepime			C				Not Reported
	Rocephine			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994799	DIRECT	Y	HO, OT			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir	Y		S	Intravenous bolus			Not Reported
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Dutasteride			C				Not Reported
	Enoxaparin			C				Not Reported
	Ezetimibe			C				Not Reported
	Pantoprazole			C				Not Reported
	Fentanyl			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17994804	DIRECT	Y	HO, OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Insulin Aspart/ Ssi			C				Not Reported
	Midodrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Fentanyl			C				Not Reported
	Phenylephrine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995004	DIRECT	Y	DE, HO			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir	S	Intravenous drip	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995169	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Insulin Nph			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995173	DIRECT	Y	DE			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir			S	Intravenous drip		1 DAY	Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995201	DIRECT	Y	OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Benzonatate 100mg Q8h			C				Not Reported
	Zyrtex 10mg Q24h			C				Not Reported
	Dexamethasone 6mg Qday			C				Not Reported
	Enoxaparin 40mg Q12h			C				Not Reported
	Famotidine 20mg Q12h			C				Not Reported
	Guaifenisen 600mg Q12h			C				Not Reported
	Insulin			C				Not Reported
	Levothyroxine			C				Not Reported

	Miralax				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17995224	DIRECT	Y	OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Sars-Cov-2 Test Positive	Remdesivir For Eua			S				Not Reported
	Acetaminophen			C				Not Reported
	Trental			C				Not Reported
	Thiamine			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Nicoderm Cq			C				Not Reported
	Theradex-M			C				Not Reported
	Novolog			C				Not Reported
	Robitussin			C				Not Reported
	Folic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Aspirin			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996089	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479988			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C	Subcutaneous	30 Mg, Bid		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Azithromycin			C	Oral	500 Mg, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996184	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0479551		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead
	Blood Plasma			C				Not Reported
	Dexamethasone			C				Not Reported
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17996766	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0480078		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypercapnia; Hypoxia; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Qd		Gilead
	Convalescent Plasma			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997341	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0480039		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Coagulopathy; Fibrin D Dimer Increased; Inflammation; Liver Injury; Prothrombin Time	Remdesivir			S	Intravenous (not otherwise specified)	Unk Unk, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

Prolonged; Serum Ferritin Increased; Transaminases Increased	Dexamethasone	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997547	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0480700		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Thrombocytopenia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17997766	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479946		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ampicillin			C				Not Reported
	Dexamethasone			C				Not Reported
	Furosemide			C				Not Reported
	Sertraline			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17998717	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Lacrimation Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17998751	DIRECT	Y				16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Famotadine			C				Not Reported
	Azithromycin			C				Not Reported
	Ondansetron			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17998765	DIRECT	Y	DE			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoxia; Pulseless Electrical Activity	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17998772	DIRECT	Y				32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17998777	DIRECT	Y				76 YR	Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phlebitis	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17998781	DIRECT	Y	DE			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lactic Acidosis; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Heparin Sodium			C				Not Reported
	Cefuroxime Axetil			C				Not Reported
	Vancomycin			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2020	17998787	DIRECT	Y	DE			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Enoxaparin 40 Mg Daily			C				Not Reported
	Enoxaparin 40 Mg Bid			C				Not Reported
	Furosemide 20 Or 40 Mg			C				Not Reported
	Carvediol 25mg Bid			C				Not Reported
	Ceftriaxone 2 Gm Daily			C				Not Reported
	Azithromycin 500mg Daily			C				Not Reported
	Levothyroxine 88mcg Daily			C				Not Reported
	Escitalopram 20 Mg Daily			C				Not Reported
	Aspirin 325 Mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17910384	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0472974		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Blood Creatinine Increased; Blood Pressure Decreased; Death; Encephalopathy; Pneumonia Bacterial; Renal Failure; Renal Tubular Necrosis; Respiratory Failure; Sepsis; Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Guaifenesin And Dextromethorphan			C		Unk		Not Reported
	Hydrocodone/Acetaminophen			C		Unk		Not Reported
	Orphenadrine			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Lubricant Eye Ointment			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Succinylcholine [Suxamethonium]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999429	DIRECT	Y	OT			38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choking Sensation; Dyspnoea; Lip Swelling	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Azithromycin 500mg Daily			S				Not Reported
	Rocephin 1g Twice Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Zyrtec 10mg Daily			C				Not Reported
	Duo Nebs			C				Not Reported
	Amlodipine 5mg Daily			C				Not Reported
	Ascorbic Acid 500mg Q12			C				Not Reported
	Colace			C				Not Reported
	Lovenox 40mg Daily			C				Not Reported
	Flonase Daily			C				Not Reported
	Singulair 10mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999519	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Dispensing Error; Product Preparation Error; Product Preparation Issue	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	17999532	DIRECT	Y	OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S			2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000460	DIRECT	Y				66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Arrest; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Linezolid			C				Not Reported
	Losartan			C				Not Reported
	Meropenem			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Nitroglycerin Topical			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Propofol Infusion			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Vancomycin			C				Not Reported
	Acetaminophen			C				Not Reported
	Hydrocodone/Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000529	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Arrest; Cardio-Respiratory Arrest; Haemodynamic Instability	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Albuterol Neb			C				Not Reported
	Levaquin 750mg/150ml Iv Q24h			C				Not Reported
	Losartan 100mg 1qd			C				Not Reported
	Solu-Medrol 80 Iv Push			C				Not Reported
	Decadron 6mg Qd			C				Not Reported
	Furosemide 40mg Once			C				Not Reported
	Etomidate 10 Mg Once			C				Not Reported

	Hydrochlorothiazide 25mg 1qd	C		Not Reported
	Heparin 5,000 Units	C		Not Reported
	Lorazepam 1mg	C		Not Reported
	Pantoprazole 40mg Daily	C		Not Reported
	Fentanyl 50mcg Q1hprn	C		Not Reported
	Humalog 6 Units Once	C		Not Reported
	Midazolam	C		Not Reported
	Epinephrine 1mg Iv	C		Not Reported
	Norepinephrine 16mg Iv	C		Not Reported
	Phenelyephrine 10mg Iv	C		Not Reported
	Vasopressin 20 Units Iv	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000543	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Miralax			C				Not Reported
	Lactated Ringer			C				Not Reported
	Warfarin			C				Not Reported
	Norepinephrine 8 Mg			C				Not Reported
	Insulin Glargine			C				Not Reported
	Famotidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000773	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479976		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Swelling; Thrombotic Thrombocytopenic Purpura	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18000951	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0480889		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead
	Allopurinol			C				Not Reported
	Methotrexate			C				Not Reported
	Pravastatin			C				Not Reported
	Valsartan			C				Not Reported
	Nabumetone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18001006	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0480755		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004849	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Aromatic Inhaler			C				Not Reported
	Benzanotate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Tussionex			C				Not Reported
	Dexamethasone			C				Not Reported

	Famotidine			C					Not Reported
	Guanfenesin			C					Not Reported
	Heparin			C					Not Reported
	Hydralazine			C					Not Reported
	Metoprolol			C					Not Reported
	Nortriptyline			C					Not Reported
	Odnansetron			C					Not Reported
	Potassium Bicarbonate			C					Not Reported
	Temazepam			C					Not Reported
	Terazosin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004869	DIRECT	Y	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004873	DIRECT	Y	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Urinary Tract Infection	Remdesivir			S	Intravenous bolus			Not Reported
	Baclofen 5mg Peg Tid			C				Not Reported
	Benztropine 1mg Peg Bid			C				Not Reported
	Dexamethasone 6mg Po Daily			C				Not Reported
	Docusate 100mg Peg Bid			C				Not Reported
	Enoxaparin 40mg Subcut Daily			C				Not Reported
	Ferrous Sulfate 325mg Peg Daily			C				Not Reported
	Gabapentin 300mg Peg Bid			C				Not Reported
	Heparin 5,000 Unit Subcut Q8h			C				Not Reported
	Lacosamide 150mg Peg Bid			C				Not Reported
	Levetiracetam 1000mg Peg Bid			C				Not Reported
	Levofloxacin 750mg Iv Q24h			C				Not Reported
	Linezolid 600mg Iv Q12h			C				Not Reported
	Magnewsium Hydroxide 8%			C				Not Reported

		Susp 30ml Oral Bid								
		Mirtazapine 30mg Peg Qbedtime			C					Not Reported
		Olanzapine 20mg Peg Bid			C					Not Reported
		Prazosin 1mg Peg Qbedtime			C					Not Reported
		Senna 8.6mg Peg Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004892	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Eye Irritation; Infusion Related Reaction; Nausea	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Enoxaparin 40mg Subq Q24h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004899	DIRECT	Y				82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Atrial Fibrillation; Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY	Gilead
	Azithromycin 500 Mg Po Daily			C				Not Reported
	Ceftriaxone 1 Gram Iv Q24h			C				Not Reported
	Famotidine 20 Mg Iv Q12h			C				Not Reported
	Methylprednisolone 20 Mg Iv Q6h			C				Not Reported
	Fentanyl 50 Mcg/Hr			C				Not Reported
	Heparin 1200 Unit/Hr			C				Not Reported
	Norepinephrine 4 Mg/250 Ml Titrated			C				Not Reported
	Propofol 20 Mcg/Kg/Min			C				Not Reported
	Amiodarone 450 Mg/250 Ml Titrated			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004907	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Nausea	Remdesivir			S	Intravenous bolus			Not Reported
	Budesonide 0.5mg Neb Q12h			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Docusate 100mg Po Bid			C				Not Reported
	Insulin Glargine 10 Unit Subcut Qbedtime			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Senna 8.6mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004916	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Cirrhosis; Hepatic Steatosis; Hyperlipidaemia	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Not Reported
	Ascorbic Acid 500mg Po Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Lactulose 20g Po Q6h			C				Not Reported
	Rifaximin 550mg Po Bid			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004976	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S	Intravenous bolus			Not Reported
	Acorbic Acid 500mg Oral Daily			C				Not Reported
	Azithromycin 500mg Daily			C				Not Reported
	Ceftriaxone 2g Iv Daily			C				Not Reported
	Clonazepam 0.5mg Oral Bid			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Enoxaparin 40mg Subcut Daily			C				Not Reported
	Hydrochlorothiazine 12.5mg Oral Daily			C				Not Reported
	Levothyroxine 137mcg Oral Daily			C				Not Reported

		Methocarbamol 750mg Oral Qid			C						Not Reported
		Valsartan 80mg Oral Daily			C						Not Reported
		Zinc Sulfate 220mg Oral Daily			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004983	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin 500 Mg Iv Q24h			C				Not Reported
	Cefepime 2 Gm Iv Q12h			C				Not Reported
	Dexamethasone 6 Mg Iv Q24h			C				Not Reported
	Famotidine 20 Mg Iv Q12h			C				Not Reported
	Heparin Sodium 5,000 Units Sq Q8h			C				Not Reported
	Magnesium Sulfate 4 Gm Iv			C				Not Reported
	Vancomycin			C				Not Reported
	Hydromorphone Iv			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004990	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardio-Respiratory Arrest	Remdesivir			S	Intravenous bolus			Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Budesonide 0.5mg Nebulized Bid			C				Not Reported
	Cefepime 2mg Iv Q12h			C				Not Reported
	Ceftriaxone 2g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Docusate 100mg Oral Bid			C				Not Reported
	Pantoprazole 40mg Oral Daily			C				Not Reported
	Senna 8.6mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18004996	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S				Gilead
	Senna			C				Not Reported
	Famotidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18005004	DIRECT	Y				46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Condition Aggravated; Nonalcoholic Fatty Liver Disease; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500 Mg Po Daily			C				Not Reported
	Ceftriaxone 1 Gram Iv Q24h			C				Not Reported
	Dexamethasone 4 Mg Iv Daily			C				Not Reported
	Doxycycline 100 Mg Po Bid			C				Not Reported
	Guaifenesin Er 600 Mg Po Bid			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18005627	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S				Not Reported
	Fentanyl			C				Not Reported
	Propotol			C				Not Reported
	Tylenol			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Famotidine			C				Not Reported
	Atrvastin			C				Not Reported

	Enoxaparin			C						Not Reported
	Piperacillin-Tazobactam			C						Not Reported
	Heparin			C						Not Reported
	Zofran			C						Not Reported
	Calquence			C						Not Reported
	Lasix			C						Not Reported
	Potassium Chloride Fluid			C						Not Reported
	Sodium Chloride Fluid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	18005852	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Infusion Related Reaction	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17867998	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469207		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol;Ipratropium			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Sennosides			C		Unk		Not Reported
	Docusate			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Epoprostenol			C				Not Reported
	Norepinephrine			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Midodrine			C		Unk		Not Reported
	Ampicillin			C		Unk		Not Reported

	Metolazone	C	Unk		Not Reported
	Ketamine	C	Unk		Not Reported
	Hydromorphone	C	Unk		Not Reported
	Cisatracurium	C	Unk		Not Reported
	Tylenol	C			Not Reported
	Acetaminophen	C			Not Reported
	Acetazolamide	C			Not Reported
	Ampicillin And Sulbactam	C			Not Reported
	Aspirin [Acetylsalicylic Acid]	C			Not Reported
	Calcium Gluconate	C			Not Reported
	Enoxaparin	C			Not Reported
	Insulin Nph [Insulin Isophane Bovine]	C			Not Reported
	Lorazepam	C			Not Reported
	Oxycodone	C			Not Reported
	Potassium	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17877788	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470621		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Arrest; Covid-19; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Kayexalate			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Rocuronium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17877916	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470625		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Hypoxia; Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Convalescent Plasma			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Tocilizumab			C				Not Reported
	Acetaminophen			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Tmp-Smx			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17886205	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0471139		90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Codeine And Guaifenesin			C		Unk		Not Reported
	Docusate			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Levetiracetam			C		Unk		Not Reported

	Levothyroxine	C	Unk		Not Reported
	Multivitamin [Vitamins Nos]	C	Unk		Not Reported
	Pantoprazole	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17887728	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469658		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Symbicort			C				Not Reported
	Asa			C				Not Reported
	Lipitor [Atorvastatin]			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Zetia			C				Not Reported
	Insulin			C				Not Reported
	Albuterol Sulfate			C				Not Reported
	Bumex			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Gabapentin			C				Not Reported
	Glipizide			C				Not Reported
	Metoprolol			C				Not Reported
	Oxycodone			C				Not Reported
	Santyl			C				Not Reported
	Toujeo Solostar			C				Not Reported
	Losartan			C				Not Reported
	Tylenol			C				Not Reported
	Proventil Hfa [Salbutamol Sulfate]			C				Not Reported
	Ventolin Hfa			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Bisacodyl			C				Not Reported
	Dextrose			C				Not Reported
	Dyclonine			C				Not Reported
	Ezetimibe			C				Not Reported
	Heparin			C				Not Reported
	Honey			C				Not Reported
	Insulin Lispro			C				Not Reported
	Magnesium Hydroxide			C				Not Reported

	Mirtazapine			C						Not Reported
	Morphine			C						Not Reported
	Zofran Melt			C						Not Reported
	Sodium Chloride			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17892605	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0471871		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypoxia; Tachycardia; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Diphenhydramine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Zinc Gluconate			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17902208	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470939		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Bilirubin Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin			C				Not Reported
	Cisatracurium			C				Not Reported
	Sennosides			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported

	Fentanyl	C	Not Reported
	Furosemide	C	Not Reported
	Insulin	C	Not Reported
	Ketamine	C	Not Reported
	Methylprednisolone	C	Not Reported
	Norepinephrine	C	Not Reported
	Zosyn	C	Not Reported
	Propofol	C	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Not Reported
	Piperacillin & Tazobactam	C	Not Reported
	Potassium	C	Not Reported
	Prednisone	C	Not Reported
	Vancomycin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	17964459	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477229		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006250	DIRECT	Y	OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Aspirin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lovenox			C				Not Reported
	Lopressor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006415	DIRECT		OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Clonidine 0.1mg Po Q6h Prn			C				Not Reported
	Alprazolam 0.25mg Po Qhs Prn			C				Not Reported
	Tocilizumab Iv 800mg Once			C				Not Reported
	Ascorbic Acid 500mg Po Bid			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported
	Dexamethasone 6mg Ivp Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006881	DIRECT	Y	OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous bolus	Other Frequency:X 1;		Gilead
	Methylprednisilone			C				Not Reported
	Fentanyl			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006887	DIRECT	Y				54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Respiratory Disorder; Transaminases Increased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006892	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006963	DIRECT	Y				75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen 1000 Mg Po Q8h			C				Not Reported
	Aspirin Chewable 81 Mg Po Daily			C				Not Reported
	Aztreonam 2,000 Mg Iv Q8h			C				Not Reported
	Clindamycin 600 Mg Iv Q8h			C				Not Reported
	Dexamethasone 6 Mg Iv Daily			C				Not Reported
	Enoxaparin 40 Mg Subq Nightly			C				Not Reported
	Breo Ellipta 200/25 Mcg 1 Puff Inh Daily			C				Not Reported
	Lactobacillus Capsule Po Twice Daily			C				Not Reported
	Lidocaine 5% Transdermal Patch Daily			C				Not Reported
	Pantoprazole 40 Mg Iv Daily			C				Not Reported
	Polyethylene Glycol 17 G Po Daily			C				Not Reported
	Potassium Chloride 40 Meq Iv Once			C				Not Reported
	Senna-Docusate 8.6/50 Mg Po Daily			C				Not Reported
	Spiriva Inhalation Capsule 18 Mcg Daily			C				Not Reported
	Remdesivir Injection			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006967	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY	Gilead
	Dexamethasone Iv			C				Not Reported
	Amiodarone Iv			C				Not Reported
	Phenylephrine Iv			C				Not Reported
	Norepinephrine			C				Not Reported
	Vecuronium			C				Not Reported
	Midazolam Iv			C				Not Reported
	Vasopressin			C				Not Reported
	Propofol			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18006971	DIRECT	Y				68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Abscess; Leukocytosis; Peritonitis; Pneumoperitoneum	Tocilizumab			S	Intravenous bolus	Other Frequency:Once;		Not Reported
	Remdesivir			S				Not Reported
	Dexamethasone 6mg Po Daily			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18007445	DIRECT	Y	OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S			5 DAY	Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010787	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0481389		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Renal Impairment	Remdesivir			S	Unknown	Unk		Gilead
	Sulfasalazine			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Doxazosin			C		Unk		Not Reported
	Benazepril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18010799	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0481317		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012558	DIRECT	Y	DE			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Covid-19 Pneumonia; Dyspnoea; Tachypnoea	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012559	DIRECT	Y				46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extravasation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012560	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Malfunction; Product Dose Omission Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012572	DIRECT	Y	DE			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Asthenia; Blood Bilirubin Increased; Blood Creatinine Increased; Cardiac Arrest; Confusional State; Diarrhoea; Fall; Hypotension; Hypothermia; Nausea; Pulmonary Oedema; Respiration Abnormal; Respiratory Arrest; Respiratory Failure; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012577	DIRECT	Y	HO			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Albuterol Mdi			C				Not Reported
	Amlodipine			C				Not Reported
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported

		Enoxaparin			C					Not Reported
		Furosemide			C					Not Reported
		Lidoderm Patch			C					Not Reported
		Metoprolol			C					Not Reported
		Pantoprazole			C					Not Reported
		Rocephin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012582	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Glomerular Filtration Rate Decreased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012588	DIRECT	Y	OT			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012595	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Sars-Cov-2 Antibody Test Positive; Therapy Cessation	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012601	DIRECT	Y	DE			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Palliative Care	Remdesivir			S	Intravenous drip			Gilead
	Dexmedetomidine			C				Not Reported
	Insulin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012606	DIRECT	Y	DE			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip			Gilead
	Cisatracurium			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin			C				Not Reported
	Ketamine			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012608	DIRECT	Y	DE			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012610	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Anakinra			C				Not Reported

	Dexamethasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012616	DIRECT	Y	HO			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Pancreatitis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Escitalopram			C				Not Reported
	Toprol X L			C				Not Reported
	Protonix			C				Not Reported
	Humalog Sliding Scale			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012811	DIRECT	Y				31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Transaminases Increased	Remdesivir			S	Intravenous bolus			Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2020	18012935	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported

Increased; Therapy Interrupted

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18012653	DIRECT	Y				59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18012654	DIRECT	Y	DE			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18012659	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Infusion Related Reaction	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;	5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18012667	DIRECT	Y				32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chills; Chills; Transaminases Increased	Remdesivir	Y	S	Intravenous bolus	Other Frequency:One Time- Loading;	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2020	18012675	DIRECT		LT, OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	18012622	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased; Thrombocytopenia	Remdesivir			S	Intravenous bolus			Gilead
	Decadron 6mg Iv Daily			C				Not Reported
	Actemra 400mg Iv X One			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2020	18012626	DIRECT		OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Remdesivir 200 Mg Iv X1			C				Not Reported
	Remdesivir 100 Mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17812574	EXPEDITED (15-DAY)		DE, HO, OT	GB-PFIZER INC-2020198894		61 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Multiple Organ	Spironolactone			S	Oral	50 Mg, 2x/Day (100mg Per		Pfizer

Dysfunction Syndrome				Day)	
	Spironolactone	S		Unk	Pfizer
	Furosemide	S	Intravenous (not otherwise specified)	40 Mg	Not Reported
	Furosemide	S	Intravenous (not otherwise specified)	40 Mg, 2x/Day (80 Mg Per Day)	Not Reported
	Furosemide	S	Intravenous (not otherwise specified)	20 Mg	Not Reported
	Furosemide	S	Intravenous (not otherwise specified)	40 Mg	Not Reported
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, 1x/Day	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Ipratropium	C		Unk	Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Co-Amoxiclav [Amoxicillin; Clavulanate Potassium]	C		Unk	Not Reported
	Lansoprazole	C		Unk	Not Reported
	Paracetamol	C		Unk	Not Reported
	Paracetamol	C			Not Reported
	Midazolam	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Metoclopramide	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Metoclopramide	C			Not Reported
	Morphine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Morphine	C			Not Reported
	Salbutamol	C	Respiratory (inhalation)	Unk	Not Reported
	Noradrenaline [Norepinephrine]	C		Unk	Not Reported
	Rocuronium	C	Intravenous (not otherwise specified)	Unk	Not Reported

Rocuronium	C			Not Reported
Piperacilin/Tazobactam	C		Unk	Not Reported
Erythromycin	C	Intravenous (not otherwise specified)	Unk	Not Reported
Heparin	C	Subcutaneous	Unk	Not Reported
Vasopressin	C		Unk	Not Reported
Fentanyl	C	Intravenous (not otherwise specified)	Unk	Not Reported
Mupirocin	C		Unk	Not Reported
Carbocisteine	C		Unk	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Senna [Sennoside A+B]	C		Unk	Not Reported
Sodium Chloride	C		Unk	Not Reported
Vancomycin	C		Unk	Not Reported
Sildenafil	C		Unk	Not Reported
Pabrinex [Ascorbic Acid;Benzyl Alcohol;Nicotinamide;Pyridoxine Hydroch	C	Intravenous (not otherwise specified)	Unk	Not Reported
Budesonide	C	Respiratory (inhalation)	Unk	Not Reported
Enoxaparin	C	Subcutaneous	Unk	Not Reported
Acetylcysteine	C	Respiratory (inhalation)	Unk	Not Reported
Movicol Plain	C		Unk	Not Reported
Prosource Tf	C		Unk	Not Reported
Milrinone	C		Unk	Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	Unk	Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	Unk	Not Reported
Methylprednisolone	C		Unk	Not Reported

	Atracurium			C	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	17927793	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0474348		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012114	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	BE-CELLTRION INC. -2020BE024090			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic; Respiratory Failure	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Cetirizine			C		Unk		Not Reported
	Thyroxine			C	Oral	Unk		Not Reported
	Calciumcarbonaat			C	Oral	Unk		Not Reported
	Livial			C	Oral	Unk		Not Reported
	Medrol [Methylprednisolone]			C	Oral	Unk		Not Reported
	Omeprazol [Omeprazole]			C		Unk		Not Reported
	Domperidone Flamingo			C	Oral	Unk		Not Reported
	Aldactone [Spironolactone]			C	Oral	Unk		Not Reported

	Xanax			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014120	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014165	DIRECT	Y	HO, OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Hyperhidrosis; Infusion Related Reaction; Nausea; Vomiting	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014188	DIRECT	Y	DE			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Creatinine Increased; Cardio-Respiratory Arrest; Pulseless Electrical Activity	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Ceftriaxone			C				Not Reported
	Fentanyl Drip 20 Mcg/Ml			C				Not Reported
	Norepinephrine Drip 8mg/250ml			C				Not Reported
	Propofol Drip 1000mg/100ml			C				Not Reported
	Vasopressin Drip 20 Units/100ml			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Ascorbic Acid 500mg Tab			C				Not Reported
	Vitamin D3 5000units Cap			C				Not Reported
	Doxycycline 100mg Cap			C				Not Reported
	Enoxaparin 80mg Inj			C				Not Reported

	Famotidine 20mg Inj	C	Not Reported
	Novolog 100units/Ml Sliding Scale	C	Not Reported
	Levemir	C	Not Reported
	Nitroglycerin 0.4mg S/L Tab	C	Not Reported
	Zinc Sulfate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014193	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;	1 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014196	DIRECT	Y	OT			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014202	DIRECT	Y				87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014233	DIRECT	Y				48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chills; Diarrhoea; Dizziness; Fatigue; Presyncope; Sinus Tachycardia; Unresponsive To Stimuli; Vomiting	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Frequency: Am		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014245	DIRECT	Y	OT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014251	DIRECT	Y	OT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014254	DIRECT	Y	DE			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage Intracranial	Remdesivir			S	Intravenous bolus			Gilead
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014258	DIRECT	Y	DE			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure; Renal Replacement Therapy	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014263	DIRECT	Y	DE			69 YR	Male	XQZ

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Covalescent Plasma			C				Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014268	DIRECT	Y	LT, OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Disease Progression	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Regular Insulin			C				Not Reported
	Protonix			C				Not Reported
	Lasix			C				Not Reported
	Nystatin			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014273	DIRECT	Y				59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered; Liver Function Test Increased; Product Dispensing Error	Remdesivir			S				Gilead
	Aspirin 81 Mg Daily			C				Not Reported
	Dexamethasone 6mg Daily			C				Not Reported
	Albuterol Inhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014279	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Gilead
	Covid Antibody Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014283	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Tocilizumab (Tocilizumab 20mg/Ml Inj, Soln, 4ml)			S	Intravenous (not otherwise specified)	Frequency: Once		Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014292	DIRECT	Y	DE			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Complication; Haemorrhagic Stroke	Remdesivir			S				Not Reported
	Aspirin 81 Mg Daily			C				Not Reported
	Calcium Chloride 19 Iv X1			C				Not Reported
	Cefepime 19 Iv Q8h			C				Not Reported

	Peridex Mouth Wash 15 Ml Bid	C	Not Reported
	Dexamethasone 6 Mg Lv Daily	C	Not Reported
	Epinephrine 0.1mg/Kg Le1	C	Not Reported
	Famotidine 20 Mg Lv Daily	C	Not Reported
	Furosemide 40 Mg Iv Q12h	C	Not Reported
	Metoclopramide 5 Mg Lv Q8h	C	Not Reported
	Midazolam Lv Continuous Infusion Titrated	C	Not Reported
	Esmolol Iv Continuous Infusion Titrated	C	Not Reported
	Fentanyl Lv Continuous Infusion Titrated	C	Not Reported
	Insulin Lv Continuous Infusion Titrated	C	Not Reported
	Norepinephrine Lv Continuous Infusion Titrated	C	Not Reported
	Hypertonic Saline Lv Continuous Infusion	C	Not Reported
	Ns Continuous Infusion 20ml/Hr	C	Not Reported
	Albumin 5% 250 Ml X 2	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014295	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014315	DIRECT	Y	HO, LT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014631	DIRECT	Y				59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Infusion Issue; Product Dose Omission Issue; Wrong Technique In Device Usage Process	Remdesivir			S				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Combivent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014674	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Gastrointestinal Haemorrhage; Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014675	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; General Physical Health Deterioration; Hypotension; Renal Failure; Renal Replacement Therapy	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014678	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir			S				Not Reported

Increased; Therapy Cessation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014683	DIRECT	Y	HO			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir Eua			S	Intravenous drip	Other Frequency:One Loading Dose;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014688	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014693	DIRECT	Y	OT			90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported
	Levophed			C				Not Reported
	Precedex			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014698	DIRECT	Y	OT			21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Maternal	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported

Exposure During Pregnancy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014923	EXPEDITED (15-DAY)			US-GILEAD-2020-0481995		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18017847	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0481381		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Vomiting	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Doxycycline			C		Unk		Not Reported
	Plasma			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18018077	DIRECT	Y				43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip		3 DAY	Gilead
	Remdesivir	Y		S	Intravenous drip		2 DAY	Gilead
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Coreg			C				Not Reported
	Ceftriaxone			C				Not Reported
	Lovenox			C				Not Reported
	Cellcept			C				Not Reported
	Nifedipine			C				Not Reported
	Protonix			C				Not Reported
	Prednisone			C				Not Reported
	Tacrolimus			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18018090	DIRECT	Y	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Serum Ferritin Increased	Remdesivir			S	Intravenous (not otherwise specified)		30 MIN	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18018098	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500 Mg Daily			C				Not Reported
	Albuterol Hfa Inhaler			C				Not Reported
	Cholecalciferol 2000 Units Daily			C				Not Reported
	Cyanocobalamin 1000 Mcg Daily			C				Not Reported
	Dexamethasone 6 Mg Daily			C				Not Reported
	Dicyclomine 20 Mg Four Times Daily			C				Not Reported
	Enoxaparin 40 Mg Daily			C				Not Reported
	Escitalopram 5 Mg Daily			C				Not Reported
	Famotidine 20 Mg Two Times Daily			C				Not Reported
	Loratadine 10 Mg Daily			C				Not Reported
	Prenatal Plus Vitamin Daily			C				Not Reported
	Pseudoephedrine 30 Mg Four Times Daily			C				Not Reported
	Verapamil 240 Mg Daily			C				Not Reported
	Zinc Sulfate 220 Mg Daily			C				Not Reported
	Acetaminophen 650 Mg Every 4			C				Not Reported

Hours As Needed

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18018101	DIRECT	Y	OT			92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18018164	DIRECT	Y	OT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Aromatic Inhaler			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaperin			C				Not Reported
	Ipratropium Bromide			C				Not Reported
	Mometasone			C				Not Reported
	Ondansetron			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18018360	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18019094	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Gilead
	Actemra			S	Intravenous drip			Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18019213	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Condition Aggravated; Hypoxia; Sinus Node Dysfunction	Remdesivir			S	Intravenous bolus			Gilead
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Pantoprazole			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Dexamethasone			C				Not Reported
	Potassium Chloride			C				Not Reported
	Butalbital/Apap/Caffeine			C				Not Reported
	Apap			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17861932	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469014		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Dyspnoea; Hyperphosphataemia; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Norepinephrine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ns			C	Intravenous (not otherwise specified)	100 Ml/Hr		Not Reported

Ceftriaxone	C	Intravenous (not otherwise specified)	2 G	Not Reported
D5lrs	C	Intravenous (not otherwise specified)	125 Ml/Hr	Not Reported
Doxycycline	C	Intravenous (not otherwise specified)	100 Mg	Not Reported
Fentanyl	C	Intravenous (not otherwise specified)	Unk	Not Reported
Heparin	C	Intravenous (not otherwise specified)	Unk	Not Reported
Insulin Regular Hm	C	Intravenous (not otherwise specified)	Unk	Not Reported
Insulin Regular Hm	C		7 Units	Not Reported
Zosyn	C	Intravenous (not otherwise specified)	2.25 G	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Albuterol Hfa	C	Respiratory (inhalation)	2 Puff	Not Reported
Amlodipine	C	Oral	5 Mg	Not Reported
Ascorbic Acid	C	Oral	500 Mg	Not Reported
Atorvastatin	C	Oral	20 Mg	Not Reported
Bupropion	C	Oral	300 Mg	Not Reported
Buspirone	C	Other	10 Mg	Not Reported
Cholecalciferol	C	Other	1000 Units	Not Reported
Famotidine	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
Novolog	C	Subcutaneous	Unk	Not Reported
Insulin Detemir	C	Subcutaneous	9 Units	Not Reported
Ketamine	C	Intravenous (not otherwise specified)	100 Mg	Not Reported
Lorazepam	C	Intravenous (not otherwise specified)	1 Mg	Not Reported

	Midazolam			C	Intravenous (not otherwise specified)	5 Mg		Not Reported
	Morphine			C	Intravenous (not otherwise specified)	2 Mg		Not Reported
	Rocuronium			C	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Thiamine			C	Oral	100 Mg		Not Reported
	Zinc Sulfate			C	Oral	220 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17892588	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470679		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Chills; Heart Rate Decreased; Hyperhidrosis; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Heparin			C	Subcutaneous	7500 Units		Not Reported
	Ipratropium Bromide And Albuterol Sulfate			C	Respiratory (inhalation)	1 Puff		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Morphine			C				Not Reported
	Ns			C				Not Reported
	Ondansetron			C				Not Reported
	Pravastatin			C				Not Reported
	Thiamine			C				Not Reported
	Iohexol			C				Not Reported
	Quetiapine [Quetiapine Fumarate]			C	Oral	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17948842	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475659		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C				Not Reported
	Hydrocortisone			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Vancomycin			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Heparin			C				Not Reported
	Norepinephrine			C				Not Reported
	Humalog			C				Not Reported
	Zinc			C				Not Reported
	Versed			C				Not Reported
	Meropenem			C				Not Reported
	Micafungin			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17949327	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475661		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Heparin			C	Intravenous (not otherwise specified)	Unk		Not Reported

	Fentanyl	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Rocuronium	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Levophed	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Vasopressin	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Neosynephrine	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Plasma	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17949328	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475657		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Apixaban			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc			C				Not Reported
	Cholecalciferol			C				Not Reported
	Docusate			C				Not Reported
	Selenium			C				Not Reported
	Famotidine			C				Not Reported
	Seroquel			C				Not Reported
	Solumedrol			C				Not Reported
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported

	Midazolam	C		Not Reported
	Propofol	C		Not Reported
	Rocuronium	C		Not Reported
	Plasma	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17963319	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0476755		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Ascorbic Acid			C	Oral	1000 Mg, Bid		Not Reported
	Aspirin 81			C	Oral	81 Mg, Qd		Not Reported
	Dexamethasone			C	Oral	6 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Azithromycin			C	Oral	500 Mg, Qd		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	17986012	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0479047		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Propofol			S	Unknown			Not Reported
	Enoxaparin			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019363	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Discomfort; Infusion Site Extravasation; Infusion Site Swelling	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019365	EXPEDITED (15-DAY)		DE, OT	GB-STRIDES ARCOLAB LIMITED-2020SP008079		84 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Livedo Reticularis	Vancomycin			S	Intravenous (not otherwise specified)	1 Gram, Bid		Strides
	Piperacillin & Tazobactam			S	Intravenous (not otherwise specified)	4.5 Gram, Tid		Not Reported
	Dexamethasone			S	Oral	6 Milligram, Qd		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200, Stat		Not Reported
	Oxygen			C	Unknown	Unk		Not Reported
	Allopurinol			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Dalteparin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019366	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Therapy Interrupted	Remdesivir	Y	S	Intravenous bolus	3 DAY	Gilead
	Allopurinol		C			Not Reported
	Atorvastatin		C			Not Reported
	Dexamethasone		C			Not Reported
	Furosemide		C			Not Reported
	Gabapentin		C			Not Reported
	Heparin		C			Not Reported
	Lispro		C			Not Reported
	Insulin Nph		C			Not Reported
	Melatonin		C			Not Reported
	Pantoprazole		C			Not Reported
	Polyethylene Glycol		C			Not Reported
	Senna/Docusate		C			Not Reported
	Dexmedetomidine		C			Not Reported
	Hydromorphone		C			Not Reported
	Norepinephrine		C			Not Reported
	Propofol		C			Not Reported
	Acetaminophen		C			Not Reported
	Ondansetrol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019372	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019392	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Cessation	Remdesivir Eua			S				Not Reported
	Tocilizumab			C				Not Reported
	Zinc			C				Not Reported
	Senna			C				Not Reported
	Rocuronium			C				Not Reported
	Quetiapine			C				Not Reported
	Polyethylene Glycol			C				Not Reported

		Pentoxifylline			C					Not Reported
		Pantoprazole			C					Not Reported
		Multivitamins			C					Not Reported
		Levothyroxine			C					Not Reported
		Insulin			C					Not Reported
		Hepaine			C					Not Reported
		Aztreonam			C					Not Reported
		Atorvastatin			C					Not Reported
		Aspirin			C					Not Reported
		Ascorbic Acid			C					Not Reported
		Amlodipine			C					Not Reported
		Acetaminophen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019398	DIRECT	Y				42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Sublimaze			C				Not Reported
	Levophed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019402	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir Eua			S				Not Reported
	Aspirin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Ketamine			C				Not Reported
	Keppra			C				Not Reported

	Lorazepam	C	Not Reported
	Metronidazole	C	Not Reported
	Multivitamin	C	Not Reported
	Norepinephrine	C	Not Reported
	Pantoprazole	C	Not Reported
	Pentoxifylline	C	Not Reported
	Propofol	C	Not Reported
	Thiamine	C	Not Reported
	Vancomycin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019408	DIRECT	Y	HO			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Troponin Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019547	DIRECT		LT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Brain Death; Brain Midline Shift; Brain Oedema; Cardiac Arrest; Cerebral Haemorrhage; Creatinine Renal Clearance Decreased; Pupil Fixed; Unresponsive To Stimuli; Vomiting	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019555	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Remdesivir			S	Intravenous bolus			Gilead

Cardio-Respiratory Arrest;
Chest Discomfort;
Dyspnoea; Hypoxia;
Pharyngeal Swelling;
Swollen Tongue;
Wheezing

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18019894	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Na			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020193	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S			5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020200	DIRECT	Y				30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ast/Alt Ratio Abnormal; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020210	DIRECT	Y	HO			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Gilead
	Actemra			C				Not Reported
	Dexamethasone Inj			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18020211	DIRECT	Y	DE			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Carboxymethylcellulose Ophthalmic Drops			C				Not Reported
	Cisatracurium			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Hydralazine			C				Not Reported
	Insulin			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021105	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482478		86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Insulin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18021134	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482469		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		500 Mg, Qd		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	2 G, Bid		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg, Bid		Not Reported
	Heparin Sodium			C	Subcutaneous	5000 Units		Not Reported
	Magnesium Sulfate			C	Intravenous (not otherwise specified)	4 G		Not Reported
	Vancomycin			C		Unk		Not Reported
	Hydromorphone			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022069	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482487		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Unknown	100 Mg		Gilead
	Famotidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Sennaplant			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18022089	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469452		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Transaminases Increased	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid	C				Not Reported
	Ceftriaxone	C				Not Reported
	Dexamethasone	C				Not Reported
	Doxycycline	C				Not Reported
	Heparin	C				Not Reported
	Hydralazine	C				Not Reported
	Loperamide	C				Not Reported
	Potassium Chloride	C				Not Reported
	Sodium Chloride	C				Not Reported
	Multivitamins [Vitamins Nos]	C				Not Reported
	Ondansetron	C				Not Reported
	Dextromethorphan Hbr & Guaifenesin	C				Not Reported
	Zinc Sulfate	C				Not Reported
	Docusate;Senna	C				Not Reported
	Acetaminophen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024034	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024044	DIRECT	Y				30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Nausea; Vomiting	Remdesivir			S	Intravenous drip			Gilead
	Ascorbic Acid 2000mg Qday			C				Not Reported
	Dexamethasone 6mg Po Qday			C				Not Reported
	Enoxaparin 40mg Subq Q12h			C				Not Reported
	Zinc Sulfate 220mg			C				Not Reported

	Codeine-Guaifenesin 10-100mg Q4h Prn Cough			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024053	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024056	DIRECT	Y	HO			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024064	DIRECT	Y	OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024070	DIRECT	Y	OT			96 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024080	DIRECT	Y	OT			89 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Atrioventricular Block Second Degree; Bradycardia	Remdesivir			S	Intravenous bolus			Gilead
	Lisinopril			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024161	DIRECT	Y				88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024171	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading Dose;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024176	DIRECT	Y	OT			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024185	DIRECT	Y	DS, OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Not Reported
	Albuterol Inhaler			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Vitamin D3 2000 Units			C				Not Reported
	Dexamethasone 6 Mg			C				Not Reported
	Famotidine 20 Mg			C				Not Reported
	Zosyn 3.375 G			C				Not Reported
	Rocuronium			C				Not Reported
	Vancomycin			C				Not Reported
	Zinc Sulfate 220 Mg			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024196	DIRECT	Y	OT			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024205	DIRECT	Y	HO, OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Solu-Medrol			C				Not Reported
	Enoxaparin			C				Not Reported
	Sodium Chloride			C				Not Reported
	Doxycycline			C				Not Reported
	Ceftriaxone			C				Not Reported
	Tocilizumab			C				Not Reported
	Novolog			C				Not Reported
	Dicyclomine			C				Not Reported
	Zofran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024217	DIRECT	Y				47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Papule; Rash Pruritic; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024252	DIRECT	Y	OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Benazepril 40 Mg Po Nightly			C				Not Reported
	Budesonide-Formoterol 160-4.5 Mcg/Actuation 2 Puffs			C				Not Reported
	Calcium Carbonate 500 Mg Chewable Tablet			C				Not Reported
	Chlortahlidone 25 Mg Po Daily			C				Not Reported
	Diltiazem Er 120 Mg Po 2 Times Daily			C				Not Reported

		Hydrocodone-Acetaminophen 10-325 Mg Po 2 Times Daily Prn			C					Not Reported
		Pantoprazole 40 Mg Po Daily			C					Not Reported
		Rivaroxaban 15 Mg Po Daily			C					Not Reported
		Vitamin D 2000 Units Po 2 Times Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024261	DIRECT	Y	LT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Liver Function Test Increased; Seizure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Alprazolam			C				Not Reported
	Aripiprazole			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Levofloxacin			C				Not Reported
	Levetiracetam			C				Not Reported
	Sertraline			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024263	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cardiac Arrest; Hypotension; Inflammatory Marker Increased; International Normalised Ratio Increased; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency: 200mgx1, 100mg/D 4;		Gilead
	Aspirin Ec 81mg Po Daily			C				Not Reported
	Atorvastatin 20mg Po Qhs			C				Not Reported
	Azithromycin 500mg Iv Q24h			C				Not Reported
	Ceftriaxone 1g Iv Once			C				Not Reported
	Dexamethasone 6mg Daily			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Epinephrine Iv Continuous Infusion			C				Not Reported

		Epoprostenol Continuous Neb			C				Not Reported
		Famotidine 20mg Iv Q12h And Q24h			C				Not Reported
		Fentanyl Infusion			C				Not Reported
		Furosemide 20mg Iv Daiily			C				Not Reported
		Lantus Qhs			C				Not Reported
		Insulin Lispro Sliding Scale 4x/D			C				Not Reported
		Midazolam Iv Continuous Infusion			C				Not Reported
		Norepinephrine Infusion			C				Not Reported
		Phenylephrine Infusion			C				Not Reported
		Propofol Infusion			C				Not Reported
		Rocuronium Iv Pushes Prn For Vent Dyssynchrony			C				Not Reported
		Sodium Bicarbonate Infusion			C				Not Reported
		Vasopressin Iv Continuous Infusion			C				Not Reported
		Vecuronium Iv Continuous Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024270	DIRECT	Y	DE, LT, OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Creatinine Increased; International Normalised Ratio Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency: 200mg/D, 100mgx4;		Gilead
	Amiodarone Bolus And Infusion			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Benztropine 1mg Ng Q8h			C				Not Reported
	Cefepime 1g Iv Q6h			C				Not Reported
	Ceftriaxone 1g Iv Once			C				Not Reported
	Daptomycin 6 Mg/Kg Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Precedex Infusion			C				Not Reported
	Diazepam 5mg Iv Q6-12h			C				Not Reported
	Enoxaparin Prophy Then Treatment			C				Not Reported
	Fentanyl 25mcg Iv Prn			C				Not Reported
	Insulin Lispro Sliding Scale 4x/Day			C				Not Reported

	Culturelle Capsule Q24h	C		Not Reported
	Meropenem 500mg Iv Q6h	C		Not Reported
	Metoprolol 5mg Iv Q6h	C		Not Reported
	Norepinephrine Infusion	C		Not Reported
	Phenylephrine Infusion	C		Not Reported
	Pip/Tazo 3.375g Iv Q8h	C		Not Reported
	Sodium Bicarbonate Infusion	C		Not Reported
	Vitamin C 1000mg Daily	C		Not Reported
	Zinc Sulfate 220mg Daily	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024360	DIRECT	Y	HO			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir	Y		S				Gilead
	Acetaminophen			C				Not Reported
	Guaifenasin			C				Not Reported
	Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2020	18024375	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17882785	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469801		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aztreonam			C	Intravenous (not	2 G		Not Reported

			otherwise specified)		
	Furosemide	C	Intravenous (not otherwise specified)	20-40mg	Not Reported
	Levofloxacin	C	Intravenous (not otherwise specified)	750 Mg	Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	800 Mg	Not Reported
	Acetaminophen	C	Oral	650 Mg	Not Reported
	Albuterol [Salbutamol]	C	Respiratory (inhalation)	2.5 Mg	Not Reported
	Atropine	C			Not Reported
	Clopidogrel	C	Oral	75 Mg	Not Reported
	Docusate	C	Oral	100 Mg	Not Reported
	Heparin	C	Subcutaneous	5000 Units	Not Reported
	Levothyroxine	C	Oral	50 Mcg	Not Reported
	Midazolam	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Pantoprazole	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
	Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Acetylcysteine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17887629	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470645		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Pressure Decreased; Heart Rate Irregular	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C	Oral	500 Mg, Bid		Not Reported
	Atorvastatin			C	Oral	40 Mg		Not Reported

	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Benzonatate	C	Oral	100 Mg, Q8h		Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Codeine	C	Oral	15 Mg, Q6h		Not Reported
	Enoxaparin	C	Subcutaneous	75 Mg		Not Reported
	Guaifenesin	C	Oral	1200 Mg, Bid		Not Reported
	Heparin	C	Subcutaneous	Unk Unk, Bid		Not Reported
	Ibuprofen	C	Oral	600 Mg, Once		Not Reported
	Losartan	C	Oral	50 Mg, Qd		Not Reported
	Metoprolol Succinate	C	Oral	25 Mg, Qd		Not Reported
	Metoprolol Tartrate	C	Oral	25 Mg, Bid		Not Reported
	Zinc Sulfate	C	Oral	220 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	17940034	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473153		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Diltiazem			C				Not Reported
	Gabapentin			C				Not Reported
	Glimepiride			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Isosorbide Dinitrate			C				Not Reported
	Levothyroxine			C				Not Reported

	Methylprednisolone			C						Not Reported
	Metoclopramide			C						Not Reported
	Pantoprazole			C						Not Reported
	Zinc Sulfate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18021510	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0481896		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024742	DIRECT	Y	DE			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Agitation; Atrial Fibrillation; Lung Infiltration; Obstructive Airways Disorder; Pulse Absent; Rales; Respiratory Failure; Respiratory Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Metoprolol			C				Not Reported
	Amiodarone			C				Not Reported
	Furosemide			C				Not Reported
	Etomidate			C				Not Reported
	Rocuronium			C				Not Reported
	Midazolam			C				Not Reported
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Atorvastatin			C				Not Reported
	Insulin Determir			C				Not Reported
	Insulin Lispro			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024764	DIRECT		HO			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Arrest	Remdesivir			S	Intravenous bolus			Gilead

		Azithromycin 500 Mg Ivpb Once			C					Not Reported
		Azithromycin 250 Mg Po Daily			C					Not Reported
		Azithromycin 500 Mg Ivpb Every 24 Hours			C					Not Reported
		Ceftriaxone 1 Gram Ivpb Every 12 Hours			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024782	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus	Other Frequency:X1;		Gilead
	Actemra			S	Intravenous bolus	Other Frequency:X1;		Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024787	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mg/Dx4;		Gilead
	Acetaminophen 325mg Q6h Prn Pain 1-3. Fever			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Lantus Qhs			C				Not Reported
	Insulin Lispro Sliding Scale 4x/D			C				Not Reported
	Norepinephrine Iv Infusion			C				Not Reported
	Tocilizumab 400mg Iv X 1			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024788	DIRECT	Y	OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous drip		Gilead
	Dexamethasone	C			Not Reported
	Ceftriaxone	C			Not Reported
	Azithromycin	C			Not Reported
	Covid Convalescent Plasma	C			Not Reported
	Albuterol	C			Not Reported
	Fluticasone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024789	DIRECT	Y				21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024790	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Acetaminophen 650 Po Q6h Prn			C				Not Reported
	Ascorbic Acid 500mg Qd			C				Not Reported
	Atenolol 25mg Qd			C				Not Reported
	Atorvastatin 20 Qpm			C				Not Reported
	Bicalutamide 50mg Qd			C				Not Reported
	Dexamethasone 6mg Iv Q 24			C				Not Reported
	Famotidine 20 Mg Qd			C				Not Reported
	Heparin 5000 Sc Q8			C				Not Reported
	Tocilizumab 100 Ml Iv Once			C				Not Reported
	Levothyroxine 100mcg Qs			C				Not Reported
	Ondansteron 4mg Q8 Prn			C				Not Reported
	Zinc Sulfate 220 Mg Qd			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024809	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Liver Function Test Increased; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024816	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Eua Product			S	Intravenous bolus			Gilead
	Dexamethasone 6 Mg Iv Daily			C				Not Reported
	Tocilizumab 400 Mg Iv X2			C				Not Reported
	Cisatracurium 37.5 Mg/Hr Iv Continuous			C				Not Reported
	Fentanyl 50 Mcg/Hr Iv Continuously			C				Not Reported
	Propofol 50 Mcg/Kg/Min Iv Continuously			C				Not Reported
	Norepinephrine 5 Mcg/Min Iv Continuously			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024817	DIRECT	Y				32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18024833	DIRECT	Y	DE			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18026584	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482356		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18026641	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470338		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Blood Bilirubin Increased; Blood Creatinine Increased; Jugular Vein Thrombosis; Pneumonia; Respiratory Disorder; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Acetaminophen			C	Oral	975 Mg		Not Reported
	Acetaminophen			C	Other	975 Mg		Not Reported
	Acetaminophen			C	Other	650 Mg		Not Reported
	Acetaminophen			C	Other	650 Mg		Not Reported
	Acetaminophen			C	Other	650 Mg		Not Reported
	Acetaminophen			C	Other	650 Mg		Not Reported
	Albuterol Hfa			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Docusate			C				Not Reported
	Duloxetine			C				Not Reported
	Enoxaparin			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported

		Haloperidol			C					Not Reported
		Hydroxyzine			C					Not Reported
		Heparin			C					Not Reported
		Insulin			C					Not Reported
		Lorazepam			C					Not Reported
		Midazolam			C					Not Reported
		Norepinephrine			C					Not Reported
		Ondansetron			C					Not Reported
		Oxycodone			C					Not Reported
		Polyethylene Glycol 3350			C					Not Reported
		Pregabalin			C					Not Reported
		Propofol			C					Not Reported
		Rocuronium			C					Not Reported
		Senna S			C					Not Reported
		Succinylcholine [Suxamethonium]			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027006	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482904		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18027028	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477223			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Respiratory Failure; Suspected Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18028282	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472223		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Blood Creatinine Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa	C				Not Reported
	Aspirin (E.C.)	C				Not Reported
	Calcium Gluconate	C				Not Reported
	Vitamin D3	C				Not Reported
	Clonidine	C				Not Reported
	Famotidine	C				Not Reported
	Furosemide	C				Not Reported
	Guaifenesin	C				Not Reported
	Midodrine	C				Not Reported
	Multivitamins [Vitamins Nos]	C				Not Reported
	Potassium Chloride	C				Not Reported
	Potassium Phosphate Dibasic	C				Not Reported
	Sodium Chloride	C				Not Reported
	Sodium Phosphate	C				Not Reported
	Sulfamethoxazole And Trimethoprim	C				Not Reported
	Thiamine	C				Not Reported
	Oxycodone	C				Not Reported
	Fentanyl	C				Not Reported
	Acyclovir [Aciclovir]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029500	DIRECT	Y	DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Unresponsive To Stimuli	Remdesivir			S				Not Reported
	Apixaban			C				Not Reported
	Benzonatate			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Pantoprazole			C				Not Reported
	Vancomycin			C				Not Reported
	Apap-Codeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029545	DIRECT	Y	DE			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock	Remdesivir	Y		S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Merrem			C				Not Reported
	Montelukast			C				Not Reported
	Senna			C				Not Reported
	Spironolactone			C				Not Reported
	Vancomycin			C				Not Reported
	Amiodarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029550	DIRECT	Y	HO			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Ofirmev 1000mg/100ml			C				Not Reported
	Acetaminophen Oral			C				Not Reported
	Ascorbic Acid 500mg			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Etomidate			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Ketorolac			C				Not Reported
	Lorazepam			C				Not Reported
	Melatonin			C				Not Reported
	Midazolam			C				Not Reported
	Pantoprazole			C				Not Reported

		Propofol			C						Not Reported
		Vecuronium			C						Not Reported
		Zinc Sulfate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029557	DIRECT	Y	HO			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Lorazepam			C				Not Reported
	Melatonin			C				Not Reported
	Maalox+Lidocaine			C				Not Reported
	Maalox			C				Not Reported
	Midazolam			C				Not Reported
	Montelukast			C				Not Reported
	Cimetidine			C				Not Reported
	Pantoprazole			C				Not Reported
	Promethazine			C				Not Reported
	Propofol			C				Not Reported
	Sucralfate			C				Not Reported
	Levothyroxine			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029588	DIRECT	Y	OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading;		Gilead
	Remdesivir	Y		S	Intravenous (not			Gilead

	Tocilizumab	C	otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029595	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029605	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Pyrexia; Unresponsive To Stimuli	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Breo Ellipta			C				Not Reported
	Protonix			C				Not Reported
	Mirapex			C				Not Reported
	Incruse Ellipta			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029631	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminiophen			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Glargine Insulin			C				Not Reported
	Lispro Insulin			C				Not Reported

	0.9% Nacl			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029641	DIRECT	Y	OT			25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)		4 DAY	Gilead
	Dexamethasone Iv			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported
	Vancomycin Iv			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029648	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albumin			C				Not Reported
	Promethazine W/Codeine			C				Not Reported
	D5w			C				Not Reported
	Dig			C				Not Reported
	Norco			C				Not Reported
	Kcl			C				Not Reported
	Lorazepam			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Sod Bicarb			C				Not Reported
	Ns			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ca Gluconate			C				Not Reported
	Ceftazidime			C				Not Reported
	Vanco			C				Not Reported
	Amio			C				Not Reported
	Mag Sulfate			C				Not Reported
	Metronidazole			C				Not Reported

	Azithromycin			C						Not Reported
	Pip/Tazo			C						Not Reported
	Tocilizumab			C						Not Reported
	Vanco			C						Not Reported
	Meropenem			C						Not Reported
	K Phos			C						Not Reported
	Acetaminophen			C						Not Reported
	Bumex			C						Not Reported
	Dexamethasone			C						Not Reported
	Enoxaparin			C						Not Reported
	Guaifenesin Dm			C						Not Reported
	Haldol			C						Not Reported
	Reg Insulin			C						Not Reported
	Reglan			C						Not Reported
	Metoprolol			C						Not Reported
	Zofran			C						Not Reported
	Proamatine			C						Not Reported
	Atropine			C						Not Reported
	Epi			C						Not Reported
	Ketorolac			C						Not Reported
	Midazolam			C						Not Reported
	Succinylcholine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18029681	DIRECT	Y	OT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Duloxetine			C				Not Reported
	Atorvastatin			C				Not Reported
	Montelukast			C				Not Reported
	Dexamethasone			C				Not Reported
	Apixaban			C				Not Reported
	Insulin Aspart			C				Not Reported

	Meropenem			C						Not Reported
	Gabapentin			C						Not Reported
	Propofol			C						Not Reported
	Sodium Bicarbonate			C						Not Reported
	Lactated Ringers			C						Not Reported
	Vancomycin			C						Not Reported
	Heparin			C						Not Reported
	Norepinephrine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18030037	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482899		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Unknown	100 Mg		Gilead
	Dexamethasone			C				Not Reported
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2020	18035551	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Physical Product Label Issue; Product Administration Error; Product Label Confusion; Product Use Complaint	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Injection			S	Intravenous (not otherwise specified)	Powder For Reconstitution		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17896499	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0469667		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Death; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

	Vancomycin	S	Intravenous (not otherwise specified)	1500 Mg		Not Reported
	Genvoya	C	Oral	1 Dosage Form, Qd		Gilead
	Biktarvy	C	Oral	1 Dosage Form, Qd		Gilead
	Enoxaparin	C	Subcutaneous	30 Mg		Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17957797	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0476807		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Hydralazine			C				Not Reported
	Metoprolol			C				Not Reported
	Thiamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	17969655	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477743		91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Death; Dyspnoea; Haemoptysis; Pulmonary Congestion	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg Iv X1, Then 100 Mg Iv X 4 Days		Gilead
	Levofloxacin			C		Unk		Not Reported
	Warfarin			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031319	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031353	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Acetaminophen(Tylenol) Tablet 650 Mg			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Ceftriaxone 1 G In Ns			C				Not Reported
	Azithromycin 500 Mg In Ns			C				Not Reported
	Heparin 7,500 Unit Inj			C				Not Reported
	Dextromethorphan-Guainfenesin 20mg			C				Not Reported
	Levothyroxin Tablet 137 Mcg			C				Not Reported
	Ondansetron Disintegrating Tablet 4 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031361	DIRECT	Y	OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031365	DIRECT	Y	OT			88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir	Y		S			4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031451	EXPEDITED (15-DAY)			US-GILEAD-2020-0482855			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Preparation Error	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031615	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Papular; Scab	Remdesivir For Injection			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031625	DIRECT	Y	DE			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Coagulopathy; Disseminated Intravascular Coagulation; Ischaemic Hepatitis; Liver Disorder; Liver Function Test Increased	Remdesivir Listed On Previous Medwatch			S C				Gilead Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031630	DIRECT	Y				77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031742	DIRECT	Y				31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031745	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Erythema; Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031962	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Choking Sensation; Cough; Dyspnoea; Nausea	Remdesivir			S	Intravenous bolus			Gilead
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031968	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mg/Dx4;		Gilead
	Dexamethasone 6mg Iv Q6h Then Daily			C				Not Reported
	Enoxaparin 30mg Sq Q12h			C				Not Reported
	Famotidine 20mg Po Q12h			C				Not Reported
	Culturelle 1 Cap Daily			C				Not Reported
	Vitamin C 1 Gram Po Daily			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031980	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Renal Failure; Respiratory Failure; Septic Shock	Remdesivir			S		Other Frequency:X 1 Dose;		Gilead
	Methylprednisolone			C				Not Reported
	Cefepime			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Protonix			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18032087	DIRECT	Y	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Albuterol			C				Not Reported
	Benzonatate			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Bio-K Plus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18032093	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased; Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mgx4d;		Gilead
	Aspirin Ec 81mg Po Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Benzonatate 100mg Q8h			C				Not Reported
	Carvedilol 6.25mg Bid			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Famotidine 20mg Po Q12h			C				Not Reported
	Culturelle 1 Cap Po Daily			C				Not Reported
	Vitamin C 1000mg Daily To Bid			C				Not Reported
	Zinc Sulfate 200mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18032103	DIRECT	Y	DE			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypoxia; Pulse Absent	Remdesivir Under Emergency Use Authorization	Y		S	Intravenous bolus		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18033239	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0483276		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Benztropine [Benzatropine]			C				Not Reported

	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Daptomycin			C				Not Reported
	Dexamethasone			C				Not Reported
	Precedex			C				Not Reported
	Diazepam			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Lispro			C				Not Reported
	Culturelle			C				Not Reported
	Meropenem			C				Not Reported
	Metoprolol			C				Not Reported
	Norepinephrine			C				Not Reported
	Phenylephrine			C				Not Reported
	Piperacillin / Tazobactam			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034928	DIRECT	Y	DE			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Cardio-Respiratory Arrest	Remdesivir			S	Intravenous drip			Gilead
	Albuterol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Nph			C				Not Reported
	Novolog Insulin			C				Not Reported
	Ipratropium			C				Not Reported
	Thiamine			C				Not Reported
	Hydrocodone/Acetaminophen			C				Not Reported
	Fentanyl Continuous Infusion			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Potassium Phosphate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034929	DIRECT	Y	OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034932	DIRECT	Y	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Inflammatory Marker Increased; Pneumonia Staphylococcal; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mg/Dx4d;		Gilead
	Azithromycin 500mg Iv Daily			C				Not Reported
	Carbamazepine 200mg Po Q12h			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Enoxaparin 40mg Subq Q12h			C				Not Reported
	Famotidine 20mg Iv Q12h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Meropenem 1g Iv Q6h			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Risperidone 0.5mg Po Qhs			C				Not Reported
	Tocilizumab 400mg X 1			C				Not Reported
	Vancomycin Varying Doses			C				Not Reported
	Vitamin C 1000mg Daily			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034933	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034934	DIRECT	Y				62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Renal Impairment	Remdesivir	Y		S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034935	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034936	DIRECT	Y				75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Dispensing Error; Product Preparation Issue	Remdesivir Injection			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034938	DIRECT	Y				55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Product Preparation Issue	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034939	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Pneumonia Pseudomonal; Systemic Candida	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034940	DIRECT	Y				55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Product Dispensing Error; Product Label Issue; Product Preparation Issue	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034941	DIRECT	Y	DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip	Other Frequency:200 Mg X1, 100 Mg;		Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034942	DIRECT	Y	DE			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Cardiac Arrest; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip			Gilead
	Cefepime 2g Iv Q12h			C				Not Reported
	Dexamethasone 6 Mg Iv Qdaily			C				Not Reported
	Enoxaparin 1 Mg/Kg Sc Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034943	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Sodium Chloride 0.45% Iv			C				Not Reported
	Acetaminophen Po			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Regular Insulin Sq			C				Not Reported
	Dexamethasone Iv			C				Not Reported
	Losartan			C				Not Reported
	Docusate			C				Not Reported
	Zinc Sulfate Po			C				Not Reported
	Ascorbic Acid Po			C				Not Reported
	Cholecalciferol Po			C				Not Reported
	Multivitamin W/ Minerals Po			C				Not Reported
	Rivaroxaban			C				Not Reported
	Ceftriaxone Iv			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Furosemide Iv Push			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034944	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate	Remdesivir	Y		S	Intravenous (not			Gilead

Decreased otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034949	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Diarrhoea; Headache; Respiratory Distress	Remdesivir	Y		S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported
	Furosemide			C				Not Reported
	Iohexol			C				Not Reported
	Thiamine			C				Not Reported
	Zinc			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034950	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hepatic Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Apixaban 5 Mg Po Bid			C				Not Reported
	Ascorbic Acid 500 Mg Po Daily With Food			C				Not Reported
	Azithromycin 500 Mg Po Q24h			C				Not Reported
	Ceftriaxone 1 Gm Iv Daily			C				Not Reported
	Cholecalciferol 1,000 Iu Po Daily			C				Not Reported
	Daptomycin 450 Mg Iv Q24h			C				Not Reported
	Dexamethaxone 6 Mg Iv Daily			C				Not Reported
	Enoxaparin 90 Mg Sq Q12h			C				Not Reported
	Escitalopram 10 Mg Po Daily			C				Not Reported
	Guaifenesin Er 600 Mg Po Bid			C				Not Reported
	Levothyroxine 25 Mcg Po Daily			C				Not Reported
	Metoprolol 12.5 Mg Po Bid			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported
	Fentanyl 25 Mcg Iv Q1hr Prn Dyspena			C				Not Reported

	Sodium Bicarbonate 150 Meq/1000 Ml D5 Iv Solution 50 Ml/Hr			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18034951	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18035164	DIRECT	Y				91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Creatinine Renal Clearance Decreased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17878094	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470901		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17878265	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470883		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Covid-19 Pneumonia; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydroxychloroquine Actavis			C				Not Reported
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Metoprolol			C				Not Reported
	Rosuvastatin			C				Not Reported
	Sevelamer			C				Not Reported
	Sodium Polystyrene Sulfonate			C				Not Reported
	Plasma			C				Not Reported
	Oxygen			C				Not Reported
	Eliquis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17925062	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2020238576		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Levofloxacin			S		Unk		Pfizer
	Levofloxacin			S				Pfizer
	Meropenem			S		Unk		Pfizer
	Meropenem			S				Pfizer
	Tigecycline			S		Unk		Pfizer
	Tigecycline			S				Pfizer
	Isavuconazonium Sulfate			S		Unk		Unknown
	Isavuconazonium Sulfate			S				Unknown
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Remdesivir			S				Not Reported
	Remdesivir			S				Not Reported

	Colimycine [Colistin Sulfate]	S	Unk		Not Reported
	Colimycine [Colistin Sulfate]	S			Not Reported
	Voriconazole	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17925759	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0474420		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Potassium Increased; Blood Pressure Decreased; Death; Haematocrit Decreased; Haemoglobin Decreased; Thrombocytopenia; Vomiting	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Acetaminophen			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Docusate;Senna			C				Not Reported
	Fentanyl			C				Not Reported
	Haloperidol			C				Not Reported
	Hydrocortisone			C				Not Reported
	Insulin Regular Hm			C				Not Reported
	Ketamine			C				Not Reported
	Levetiracetam			C				Not Reported
	Lorazepam			C				Not Reported
	Metronidazole			C				Not Reported
	Midazolam			C				Not Reported
	Milk Of Magnesia			C				Not Reported
	Pantoprazole			C				Not Reported
	Quetiapine			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Sodium Chloride			C				Not Reported
	Sodium Polystyrene Sulfonate			C				Not Reported
	Trazodone			C				Not Reported
	Valproic Acid			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	17951126	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475719		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported
	Plasma			C				Not Reported
	Ceftriaxone			C				Not Reported
	Emend [Aprepitant]			C				Not Reported
	Zofran [Ondansetron]			C				Not Reported
	Compazine [Prochlorperazine Maleate]			C				Not Reported
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18020525	NON-EXPEDITED		DE, OT	US-SA-2020SA179325			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haemorrhage	Plavix			S	Unknown	Unk		Sanofi
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Baricitinib			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035516	DIRECT	Y	OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Lung Infiltration	Remdesivir	Y	S	Intravenous drip		Gilead
	Rocephin		C			Not Reported
	Azithromycin		C			Not Reported
	Vancomycin		C			Not Reported
	Zosyn		C			Not Reported
	Dexamethasone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035517	DIRECT	Y	OT			70 YR	Male	AFG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Disease Complication; Pneumonia	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Zosyn			C				Not Reported
	Solumedrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035597	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous drip			Gilead
	Solumedrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035639	DIRECT	Y				30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency: 200mgx1,100mgx4;		Gilead
	Acetaminophen 500mg Tab			C				Not Reported
	Ondansetron 4mg Iv			C				Not Reported
	Dexamethasone 6mg Iv			C				Not Reported
	Enoxaparin 40mg Syringe			C				Not Reported
	Mucinex Dm 600/30mg Tab Sr			C				Not Reported
	Acetaminophen 325mg Tab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035719	DIRECT	Y	OT			1 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Roecephin			C				Not Reported
	Zosyn			C				Not Reported
	Azithromycin			C				Not Reported
	Rocephin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035725	DIRECT	Y	DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035926	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Hypersensitivity; Feeling Abnormal; Headache; Pharyngeal Swelling; Refusal Of Treatment By Patient	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol 3350			C				Not Reported

		Zinc Sulfate			C					Not Reported
		Codeine-Guaifenesin			C					Not Reported
		Promethazine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18035933	DIRECT	Y	OT			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Infusion Site Extravasation; Infusion Site Swelling	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036176	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Oxygen Saturation Decreased; Platelet Count Increased; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mgx4d;	4 DAY	Gilead
	Acetaminophen Q6h Prn Fever			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Benzonatate 200mg Q8h			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Famotidine 20mg Po Q12h			C				Not Reported
	Advair Hfa 115/21 2 Puff Bid			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Spiriva 18mcg Inhaled Daily			C				Not Reported
	Vitamin C 1000mg Po Daily			C				Not Reported
	Zinc Sulfate 200mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036194	DIRECT	Y	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir			S	Intravenous (not	Other Frequency:Once;		Gilead

Increased; Aspartate Aminotransferase Increased; Sars-Cov-2 Test Positive			otherwise specified)		
	Remdesivir	S	Intravenous (not otherwise specified)		Gilead
	Acetaminophen	C			Not Reported
	Dexamethasone	C			Not Reported
	Docusate	C			Not Reported
	Enoxaparin	C			Not Reported
	Lamotrigine	C			Not Reported
	Lithium	C			Not Reported
	Pantoprazole	C			Not Reported
	Pramipexole	C			Not Reported
	Senna	C			Not Reported
	Trazodone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036257	DIRECT	Y	HO			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18036332	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported

	Propofol			C						Not Reported
	Vasopressin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037300	EXPEDITED (15-DAY)		DE, OT	GB-IBIGEN-2020.09028		84 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Livedo Reticularis	Oxygen			C				Not Reported
	Piperacillin & Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Tid		Not Reported
	Allopurinol			C				Not Reported
	Fexofenadine			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			S	Oral	6 Mg, Qd		Not Reported
	Omeprazole			C				Not Reported
	Dalteparin			C				Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200, Stat		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18037988	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0483702		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin (E.C.)			C				Not Reported
	Metformin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

	Epinephrine		C		Not Reported
	Epoprostenol		C		Not Reported
	Famotidine		C		Not Reported
	Fentanyl		C		Not Reported
	Furosemide		C		Not Reported
	Lantus		C		Not Reported
	Insulin Lispro		C		Not Reported
	Midazolam		C		Not Reported
	Norepinephrine		C		Not Reported
	Phenylephrine		C		Not Reported
	Propofol		C		Not Reported
	Rocuronium		C		Not Reported
	Sodium Bicarbonate		C		Not Reported
	Vasopressin		C		Not Reported
	Vecuronium		C		Not Reported
	Tocilizumab		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18038118	EXPEDITED (15-DAY)			US-GILEAD-2020-0483220			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	200 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18038968	EXPEDITED (15-DAY)		DE, OT	GB-BAUSCH-BL-2020-020115		84 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Livedo Reticularis	Dexamethasone			S	Oral			Valeant
	Piperacillin And Tazobactam			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200, Stat		Not Reported
	Oxygen			C				Not Reported

	Allopurinol			C						Not Reported
	Fexofenadine			C						Not Reported
	Atorvastatin			C	Unknown					Not Reported
	Omeprazole			C	Unknown					Not Reported
	Dalteparin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18038969	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0483273		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18039487	EXPEDITED (15-DAY)			US-GILEAD-2020-0483949		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Issue	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18040312	EXPEDITED (15-DAY)			US-GILEAD-2020-0483260		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once		Gilead
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Combivent			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18040633	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0483659		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Blood Bilirubin Increased; Blood Creatinine Increased; Cardiac Arrest; Hypotension; Hypothermia; Respiratory Arrest; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Dexamethasone			C		6 Mg, Qd		Not Reported
	Plasma, Fresh Frozen			C				Not Reported
	Oxygen			C				Not Reported
	Furosemide			C		Unk		Not Reported
	Valsartan			C		Unk		Not Reported
	Sodium Chloride 0.9%			C		500 Ml		Not Reported
	Normal Saline			C		75 Ml/Hr		Not Reported
	Albumin (Ljudski) 20%			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18040850	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483686		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous bolus	100 Mg, Once		Gilead
	Lisinopril			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042660	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042664	DIRECT	Y	HO			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Tylenol 650mg			C				Not Reported
	Azithromycin 500mg			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Enoxaparin 40mg			C				Not Reported
	Furosemide 40mg			C				Not Reported
	Levalbuterol			C				Not Reported
	Rocephin 1gm			C				Not Reported
	Morphine 2mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042688	DIRECT	Y	OT			97 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Carboxymethylcellulose Ophthalmic Drops			C				Not Reported
	Ceftaroline			C				Not Reported
	Premarin Vaginal Cream			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042704	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Laboratory Test Abnormal; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042711	DIRECT	Y	HO			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous drip		4 DAY	Gilead
	Atorvastatin			C				Not Reported
	Azithromcyin			C				Not Reported
	Dexamethasone			C				Not Reported
	Duloxetine			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Ipratropium			C				Not Reported
	Levetiracetam			C				Not Reported
	Lorazepam			C				Not Reported
	Memantine			C				Not Reported
	Meropenem			C				Not Reported
	Oxybutynin			C				Not Reported
	Succinylcholine			C				Not Reported
	Propofol			C				Not Reported
	Gapabentin			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042717	DIRECT	Y				86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous drip		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042722	DIRECT	Y	DE			1 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Cardiac Arrest;	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

Decreased Appetite; Encephalopathy; Lethargy; Malaise; Nausea; Pneumonia; Pyrexia; Respiratory Distress; Respiratory Failure; Septic Shock	Convalescent Plasma			C					Not Reported
	Azithromycin 500 Mg Iv Once Daily			C					Not Reported
	Ceftriaxone 1 Gm Iv Once Dailly			C					Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C					Not Reported
	Enoxaparin 40 Mg Sq Once Daily			C					Not Reported
	Lasix 20 Mg Iv Bid 9a, 5p			C					Not Reported
	Lasix 40 Mg Iv X 1			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042760	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Unfractionated Heparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Linezolid			C				Not Reported
	Mycophenolate			C				Not Reported
	Tacrolimus			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Sodium Bicarbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042765	DIRECT	Y				26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Pain; Peripheral Swelling; Skin	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

Discolouration

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042778	DIRECT	Y	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Laboratory Test Abnormal	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042796	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hepatic Enzyme Increased; Leukocytosis; Pneumonia Aspiration	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Hydroxychloroquine 400 Mg X 1			C				Not Reported
	Levetiracetam 500 Mg Iv Q12hr			C				Not Reported
	Zosyn 3.375 Gm Iv Q8hr			C				Not Reported
	Vancomycin 1250 Mg Iv Q18h			C				Not Reported
	Dexamethasone 20 Mg Iv Daily			C				Not Reported
	Amlodipine 5 Mg Po Once Daily			C				Not Reported
	Aspirin 81 Mg Po Once Daily			C				Not Reported
	Atorvastatin 80 Mg Po Daily			C				Not Reported
	Donepezil 10 Mg Po W/ Breakfast			C				Not Reported
	Enoxaparin 40 Mg Sq Once Daily			C				Not Reported
	Enoxaparin 100 Mg Sq Q12hr			C				Not Reported
	Enoxaparin 90 Mg Sq Q12hr			C				Not Reported
	Fluoxetine 20 Mg Po Once Daily			C				Not Reported
	Metoprolol 25 Mg Po Q12hr			C				Not Reported
	Tamsulosin 0.4 Mg Po Once Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042800	DIRECT	Y	DE			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Hypoxia; Pulmonary Function Test Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500 Mg Iv X 1			C				Not Reported
	Azithromycin 500 Mg Po Once Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Dailly			C				Not Reported
	Enoxaparin 40 Mg Sq Once Daily			C				Not Reported
	Enoxaparin 80 Mg Sq Once Daily			C				Not Reported
	Methyprednisolone 60 Mg Iv Q12hr			C				Not Reported
	Zinc Sulfate 220 Mg Po Bid			C				Not Reported
	Lantus 15 Units Sq Daily			C				Not Reported
	Lantus 20 Untis Sq Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042831	DIRECT	Y	OT			1 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypersensitivity; Rash; Swelling	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500 Mg Iv X 1			C				Not Reported
	Azithromycin 500 Mg Po Once Daily			C				Not Reported
	Ascorbic Acid 1000 Mg Po Q12h			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Diphenhydramine 25 Mg Iv X 1 Stat			C				Not Reported
	Enoxaparin 60 Mg Sq Q12hrs			C				Not Reported
	Methylprednisolone 60 Mg Iv Q6hr			C				Not Reported
	Zinc Sulfate 220 Mg Po Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042835	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Liver Function Test Increased	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042845	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Amlodipine 10 Mg			C				Not Reported
	Ascorbic Acid 1000 Mg Po Q12h			C				Not Reported
	Dexamethasone 10 Mg Iv Once Daily			C				Not Reported
	Hydroxychloroquine 400 Mg Po Daily			C				Not Reported
	Hydroxchloroquine 400 Mg Po Q12hrs			C				Not Reported
	Enoxaparin 50 Mg Sq Q12hrs			C				Not Reported
	Enoxaparin 100 Mg Sq Q12hrs			C				Not Reported
	Enoxaparin 100 Mg Sq Once Daily			C				Not Reported
	Enoxaparin 80 Mg Sq Once Daily			C				Not Reported
	Enoxaparin 70 Mg Sq Q12hrs			C				Not Reported
	Meropenem 1 Gm Q8hr			C				Not Reported
	Meropenem 500 Mg Q8hr			C				Not Reported
	Vancomycin 1 Gm Iv Q12hrs			C				Not Reported
	Vancomycin 750 Mg Iv Q12hrs			C				Not Reported
	Zinc Sulfate 220 Mg Po Bid			C				Not Reported
	Methylprednisolone 40 Mg Iv Q12hr			C				Not Reported
	Lantus 10 Units Sq Bid			C				Not Reported
	Lantus 16-24 Units Sq Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042848	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Laboratory Test Abnormal	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042873	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Pulseless Electrical Activity	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2020	18042876	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Enterobacter Pneumonia	Remdesivir	Y		S				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18038171	EXPEDITED (15-DAY)		DE, OT	GB-AUROBINDO-AUR-APL-2020-035246		84 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Livedo Reticularis	Piperacillin+Tazobactam			S	Intravenous (not otherwise specified)	13.5 Gram, Once A Day (4.5 G, Tid)		Aurobindo
	Dexamethasone			S	Oral	6 Milligram, Once A Day		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	2 Gram, Two Times A Day (1 G, Bid)		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk (200, Stat)		Not Reported
	Oxygen			C	Unknown	Unk		Not Reported
	Allopurinol			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported

	Atorvastatin			C	Unknown	Unk				Not Reported
	Omeprazole			C	Unknown	Unk				Not Reported
	Dalteparin			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18042881	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18042886	DIRECT	Y				73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Peripheral Swelling	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18042888	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dialysis; Renal Failure	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2020	18042948	DIRECT	Y	OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead

		Acetaminophne 650mg Q4h Prn			C					Not Reported
		Ascorbic Acid 1000 Mg Po Bid			C					Not Reported
		Atorvastatin 80 Mg Once Daily			C					Not Reported
		Benzonatate 200 Mg Po Q8h			C					Not Reported
		Docusate 200 Mg Po Bid			C					Not Reported
		Enoxaparin 90 Mg Sc Q12h			C					Not Reported
		Famotidine 20 Mg Iv/Po Q12h			C					Not Reported
		Fentanyl Iv Continuous Infusion			C					Not Reported
		Insulin Glargine 40 Units Sc Bedtime			C					Not Reported
		Methylprednisolone 40 Mg Iv Q6h			C					Not Reported
		Midazolam Iv Continuous Infusion			C					Not Reported
		Norepinephine Iv Continuous Infusion			C					Not Reported
		Rocuronium Continuous Iv Infusion			C					Not Reported
		Sertraline 50 Mg Po Daily			C					Not Reported
		Thiamine Mononitrate 100 Mg Po Daily			C					Not Reported
		Zinc Sulfate 220 Mg Po Bid			C					Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
19-Jul-2020	18042892	DIRECT	Y	OT			80 YR	Male	USA	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead		
	Dexamethasone			C				Not Reported		
	Cefepime			C				Not Reported		
	Propofol			C				Not Reported		
	Fentanyl			C				Not Reported		
	Diltiazem			C				Not Reported		
	Norepinephrine			C				Not Reported		
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
19-Jul-2020	18042893	DIRECT	Y	OT			40 YR	Male	USA	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Eye Irritation; Lacrimation Increased; Photophobia	Remdesivir (Eua) 100 Mg In Sodium Chloride 0.9 % 250 Ml Ivpb			S	Intravenous drip			Gilead
	Ceftriaxone 1g Q24h			C				Not Reported
	Doxycycline 100 Mg Bid			C				Not Reported
	Heparin 5000 Units Subq Bid			C				Not Reported
	Acetaminophen 1000 Mg Q8h			C				Not Reported
	Senna 17.2 Mg			C				Not Reported
	Dextromethorphan-Guaifenesin (Robitussin-Dm) 10-100 Mg/5 Ml Liquid 5 M			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2020	18042921	DIRECT	Y				42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2020	18042929	DIRECT	Y	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vecuronium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2020	18042938	DIRECT	Y				89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Lip Erythema; Lip Swelling; Lung Opacity; Oxygen Saturation Decreased; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone Oral Tablet			C				Not Reported
	Enoxaparin 30 Mg Syringe			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17866588	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470040		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	17976144	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478171		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Oxygen			C	Nasal	5 L, Q1minute		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044292	DIRECT	Y	OT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Liver Function Test	Remdesivir			S	Intravenous drip			Gilead

Increased		Dexamethasone			C					Not Reported
		Enoxaparin			C					Not Reported
		Sulfamethoxazole/Trimethoprim			C					Not Reported
		Acetaminophen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044297	DIRECT	Y	OT			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Isosorbide			C				Not Reported
	Levothyroxine			C				Not Reported
	Potassium			C				Not Reported
	Aspirin			C				Not Reported
	Apixaban			C				Not Reported
	Ceftriaxone			C				Not Reported
	Iohexol			C				Not Reported
	Acetaminophen			C				Not Reported
	Furosemide			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044300	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Metabolic Acidosis; Pulseless Electrical Activity; Respiratory Failure; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Melatonin			C				Not Reported
	Morphine			C				Not Reported
	Ocular Lubricant			C				Not Reported

		Ceftriaxone			C					Not Reported
		Midazolam			C					Not Reported
		Norepinephrine			C					Not Reported
		Propofol			C					Not Reported
		Albumin			C					Not Reported
		Lactated Ringers			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044306	DIRECT	Y				42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044312	DIRECT	Y	DE			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased	Remdesivir (Gs-574)			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044317	DIRECT					40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen 650 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044322	DIRECT	Y	HO			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Remdesivir	S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044453	DIRECT	Y				76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous drip			Not Reported
	Dexamethasone			C				Not Reported
	Rivaroxaban			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044487	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Atorvastan			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Norephinephrine Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Pitressin Drip			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18044535	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0483671		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Guaifenesin			C		Unk		Not Reported
	Multivitamin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18045238	EXPEDITED (15-DAY)		DE, OT	GB-PFIZER INC-2020274304		84 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Hypotension; Livedo Reticularis; White Blood Cell Count Decreased	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Tid 3x/Day		Pfizer
	Vancomycin Hcl			S	Intravenous (not otherwise specified)	2 G, 2x/Day		Pfizer
	Dexamethasone			S	Oral	6 Mg, Qd (Daily)		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200 Unk (Stat)		Not Reported
	Oxygen			C		Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Fexofenadine			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Dalteparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18045538	EXPEDITED (15-DAY)			US-GILEAD-2020-0483336			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Issue	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047692	DIRECT	Y				76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Prescribing Error; Wrong Product Administered	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047736	DIRECT	Y	HO			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir	Y		S	Intravenous bolus			Gilead
	Atorvastatin			C				Not Reported
	Plavix			C				Not Reported
	Dexamethasone			C				Not Reported
	Insulin			C				Not Reported
	Lasix			C				Not Reported
	Lisinopril			C				Not Reported
	Metoprolol Xl			C				Not Reported
	Proton Ix			C				Not Reported
	Lovenox			C				Not Reported
	Levaquin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047739	DIRECT	Y	RI			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Dose Omission; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047771	DIRECT	Y				80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; International Normalised Ratio Increased; Ischaemic Hepatitis	Remdesivir			S	Intravenous bolus			Gilead
	Meropenem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047777	DIRECT	Y				87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered; Product Prescribing Error	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047781	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Diprivan			C				Not Reported
	Heparin			C				Not Reported
	Versed			C				Not Reported
	Zemuron			C				Not Reported
	Sublimaze			C				Not Reported
	Sodium Chloride 0.45%			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047785	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047790	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir 200mg			S	Intravenous bolus	200mg X1 Then 100mg Daily X4		Gilead
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047806	DIRECT	Y	LT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone 6 Mg Po			C				Not Reported
	Famotidine 20 Mg Po			C				Not Reported
	Rocuronium 50 Mg Iv			C				Not Reported
	Midazolam 2 Mg Iv			C				Not Reported
	Propofol			C				Not Reported
	Succinylcholine 100 Mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047826	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; International Normalised Ratio Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047831	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18047838	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Discomfort; Infusion Site Extravasation; Infusion Site Pain	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2020	18048292	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17872381	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469304		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Plaquinol			C	Oral	Unk		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Doxycycline			C	Oral	Unk		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Vitamin C [Ascorbic Acid]			C		Unk		Not Reported
	Torsemide			C	Oral			Not Reported
	Cardizem Cd			C	Oral			Not Reported

	Lipitor [Atorvastatin]			C	Oral				Not Reported
	Protonix [Omeprazole]			C					Not Reported
	Metoprolol			C					Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Unk			Not Reported
	Actemra			C	Intravenous (not otherwise specified)	400 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17975234	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0477746		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)	6mg		Not Reported
	Enoxaparin			C	Subcutaneous	70 Mg, Bid		Not Reported
	Iohexol			C	Intravenous (not otherwise specified)	90ml		Not Reported
	Multivitamins;Minerals			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	17979289	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478652		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S		Unk		Gilead
	Amlodipine			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Carvedilol			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

Cefuroxime	C	Unk	Not Reported
Clopidogrel	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Humalog	C	Unk	Not Reported
Probiotic [Bifidobacterium Infantis;Lactobacillus Acidophilus]	C	Unk	Not Reported
Lisinopril	C	Unk	Not Reported
Potassium Chloride	C	Unk	Not Reported
Pravastatin	C	Unk	Not Reported
Acetaminophen	C	Unk	Not Reported
Haldol [Haloperidol]	C	Unk	Not Reported
Hydralazine	C	Unk	Not Reported
Effer K	C	Unk	Not Reported
Magnesium	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048688	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048691	DIRECT	Y				41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported

		Azithromycin			C					Not Reported
		Benzonatate			C					Not Reported
		Ceftriaxone			C					Not Reported
		Codeine-Guaifenasin			C					Not Reported
		Dexamethasone			C					Not Reported
		Enoxaparin			C					Not Reported
		Famotidine			C					Not Reported
		Peg 3350			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048696	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Pulseless Electrical Activity	Remdesivir			S	Intravenous bolus			Gilead
	Tylenol			C				Not Reported
	Cisatracurium			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048902	DIRECT		DE			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Fibrinogen Increased; Blood Lactate Dehydrogenase Increased; Covid-19; Diarrhoea; Drug Withdrawal Syndrome; Fibrin D Dimer Increased; Nausea; Pulseless Electrical Activity; Respiratory Distress; Serum Ferritin Increased; Vomiting	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18048962	DIRECT	Y	HO			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049335	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049365	DIRECT	Y	OT			83 YR	Male	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Norepinephrine			C				Not Reported
	Cefepime			C				Not Reported
	Midazolam			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049368	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049671	DIRECT	Y	OT			20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Azithromycin 500mg Iv Q24h			C				Not Reported
	Ceftriaxone 2g Iv Q24h			C				Not Reported
	Dexamethasone 6mg Po Q24h			C				Not Reported
	Enoxaparin 40mg Sq Q24h			C				Not Reported
	Tocilizumab 400mg Iv Once			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049679	DIRECT	Y	DS, HO			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Artery Occlusion; Cerebral Infarction	Remdesivir			S	Intravenous bolus		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049688	DIRECT	Y				33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049743	DIRECT		HO			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049788	DIRECT		OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased	Remdesivir			S				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18049795	DIRECT	Y	DS			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Aspirin 81 Mg			C				Not Reported
	Cetylpyridinium Chloride			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexamethasone			C				Not Reported
	White Petrolatum-Mineral Oil Ophthalmic Ointment			C				Not Reported
	Diltiazem			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentynal			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Multivitamin With Iron-Mineral			C				Not Reported
	Mupirocin			C				Not Reported
	Polyethylene Glycol Packet			C				Not Reported
	Sennosides			C				Not Reported
	Unjury			C				Not Reported

	Midazolam			C						Not Reported
	Norepinephrine			C						Not Reported
	Propofol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050438	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483985		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Transaminases Increased	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Albuterol [Salbutamol Sulfate]			C		Unk		Not Reported
	Fluticasone			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Plasma			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050599	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484234		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Hypertension; Hypoxia; Pulmonary Function Test Decreased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Azithromycin			C	Oral	500 Mg, Qd		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	80 Mg, Qd		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	60 Mg		Not Reported

	Zinc Sulfate	C	Oral	220 Mg, Bid		Not Reported
	Lantus	C	Subcutaneous	15 Units		Not Reported
	Lantus	C	Subcutaneous	20 Units		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18050743	EXPEDITED (15-DAY)		DE, HO	BE-SEBELA IRELAND LIMITED-2020SEB00086		68 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic; Respiratory Failure	Imuran			S		Unk		Sebela
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Aldactone			C		Unk		Not Reported
	Calcium Carbonate			C		Unk		Not Reported
	Cetrizine			C		Unk		Not Reported
	Domperidone			C		Unk		Not Reported
	Livial			C		Unk		Not Reported
	Thyroxine			C		Unk		Not Reported
	Medrol			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Xanax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18052100	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0484063			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18053342	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18053359	DIRECT	Y	RI			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Haemodialysis; Paralysis; Renal Failure; Sepsis; Therapy Cessation	Remdesivir			S				Not Reported
	Calcium Chloride			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Lantus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18053364	DIRECT	Y	DE			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hypotension	Remdesivir			S	Oral			Gilead
	Lovenox			C				Not Reported
	Atorvastatin			C				Not Reported
	Propofol			C				Not Reported
	Phytonadione			C				Not Reported
	Zosyn			C				Not Reported
	Peg			C				Not Reported
	Morphine			C				Not Reported
	Lidocaine			C				Not Reported
	Fentanyl			C				Not Reported
	Epinephrine			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18053368	DIRECT	Y	DE, HO, LT			84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18053390	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Rivaroxaban			S	Oral			Janssen
	Albuterol Inhaler			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin			C				Not Reported
	Pantoprazole			C				Not Reported
	Risperidone			C				Not Reported
	Tiotropium			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18053433	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Skin Disorder	Remdesivir Eua 100mg			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone Iv			C				Not Reported
	Enoxaparin Sq			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18053436	DIRECT	Y	DE			97 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Carboxymethylcellulose Ophthalmic Drops			C				Not Reported
	Ceftaroline			C				Not Reported
	Premarin Vaginal Cream			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18053466	DIRECT	Y	HO			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Glucose Decreased; Dysarthria; Dyspnoea; Hyperglycaemia; Lethargy; Lung Infiltration; Mental Status Changes; Pyrexia; White Blood Cell Count Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18054434	DIRECT	Y	DE			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Arrest; Heart Rate Decreased	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported

	Apixaban	C	Not Reported
	Aspirin	C	Not Reported
	Atorvastatin	C	Not Reported
	Benzonatate	C	Not Reported
	Calcitriol	C	Not Reported
	Ceftriaxone	C	Not Reported
	Chlorhexidine	C	Not Reported
	Clopidogrel	C	Not Reported
	Dexamethasone	C	Not Reported
	Diphenhydramine	C	Not Reported
	Epoetin Alfa-Epbx	C	Not Reported
	Fluconazole	C	Not Reported
	Furosemide	C	Not Reported
	Insulin Detemir	C	Not Reported
	Insulin, Regular	C	Not Reported
	Isosorbide Mononitrate	C	Not Reported
	Melatonin	C	Not Reported
	Metolazone	C	Not Reported
	Midodrine	C	Not Reported
	Mupirocin	C	Not Reported
	Norepinephrine	C	Not Reported
	Ondansetron	C	Not Reported
	Pantoprazole	C	Not Reported
	Propafenone	C	Not Reported
	Sevalamer Carbonate	C	Not Reported
	Terazosin	C	Not Reported
	Trazodone	C	Not Reported
	Vancomycin	C	Not Reported
	Venlafaxine	C	Not Reported
	Clortimazole	C	Not Reported
	Insuline Aspart	C	Not Reported
	Metroprolol Succinate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18054894	DIRECT	Y	RI			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18054943	DIRECT	Y				83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18054997	DIRECT	Y				51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18055037	DIRECT	Y	RI			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18055038	DIRECT	Y	DE			89 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not			Not Reported

Increased; Disease Progression; Glomerular Filtration Rate Decreased; Renal Impairment	otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2020	18055058	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea Increased; Disease Progression; Glomerular Filtration Rate Decreased; Renal Failure	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17925133	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0474418		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Covid-19; Dyspnoea	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Acetaminofen			C		Unk		Not Reported
	Ipratropium Bromide/Albuterol Sulfate			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Bisacodyl			C		Unk		Not Reported
	Carvedilol			C		Unk		Not Reported
	Cefazolin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

	Cholecalciferol	C	Unk		Not Reported
	Clopidogrel	C	Unk		Not Reported
	Folic Acid	C	Unk		Not Reported
	Furosemide	C	Unk		Not Reported
	Heparin	C	Unk		Not Reported
	Lidocaine	C	Unk		Not Reported
	Metoprolol	C	Unk		Not Reported
	Scopolamine [Hyoscine]	C	Unk		Not Reported
	Tamsulosin	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	17952578	EXPEDITED (15-DAY)			US-GILEAD-2020-0476285		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18015900	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0480805		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Decadron [Dexamethasone]			C		Unk		Not Reported
	Digoxin			C				Not Reported

	Fentanyl	C	Unk		Not Reported
	Lasix [Furosemide]	C			Not Reported
	Heparin [Heparin Sodium]	C	Unk		Not Reported
	Norepinephrine	C	Unk		Not Reported
	Diprivan	C	Unk		Not Reported
	Herceptin	C			Not Reported
	Perjeta	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054154	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054171	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ertapenem			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Tamsulosin			C				Not Reported
	Furosemide			C				Not Reported
	Acetaminophen			C				Not Reported
	Morphine			C				Not Reported
	Ondansetron			C				Not Reported
	Oxycodone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Budesonide			C				Not Reported
	Dexamethasone			C				Not Reported
	Finasteride			C				Not Reported
	Atorvastatin			C				Not Reported

	Escitalopram			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054175	DIRECT	Y	CA			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Drugs Affecting Foetus; Maternal Exposure Timing Unspecified	Remdesivir			S				Not Reported
	Levophed			C				Not Reported
	Heparin Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Lovenox			C				Not Reported
	Ceftriaxone			C				Not Reported
	Nimbex			C				Not Reported
	Dexamethasone			C				Not Reported
	Precedex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054179	DIRECT	Y	DE			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Cardio-Respiratory Arrest; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)		7 DAY	Gilead
	Dexamethasone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Multivitamin			C				Not Reported
	Ergocalciferol			C				Not Reported
	Zosyn			C				Not Reported
	Zyvox			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Versed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054194	DIRECT	N					Prefer not to disclose	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased	Remdesivir	S		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054412	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Albuterol			C				Not Reported
	Albuterol-Ipratropium			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Famotidine			C				Not Reported
	Melatonin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Ceftriaxone			C				Not Reported
	Thiamine			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054585	DIRECT					66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054623	DIRECT	Y	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir	Y	S	Intravenous (not otherwise specified)					Gilead
	Atorvastatin		C						Not Reported
	Acetaminophen		C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054795	DIRECT	Y				48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous bolus	Other Frequency:Once Dose;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054800	DIRECT	Y				30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading Dose;		Gilead
	Vancomycin			C				Not Reported
	Levofloxacin			C				Not Reported
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054852	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported
	Amiodarone Drip			C				Not Reported
	Atorvastatin			C				Not Reported

	Azithromycin	C			Not Reported
	Cisatracurium Drip	C			Not Reported
	Diltiazem Drip	C			Not Reported
	Enoxaparin	C			Not Reported
	Epoprostenol Neb	C			Not Reported
	Ketamine Drip	C			Not Reported
	Lorazepam Inj	C			Not Reported
	Methylprednisolone Sod Succ Inj	C			Not Reported
	Midazolam Drip	C			Not Reported
	Norepinephrine Drip	C			Not Reported
	Pantoprazole Inj	C			Not Reported
	Piperacillin-Tazobactam Ivpb	C			Not Reported
	Rivaroxaban	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054927	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484197		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Benzonatate			C				Not Reported
	Dexamethasone			C				Unknown
	Enoxaparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Bio-K Plus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18054937	DIRECT	Y				63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Piperacillin-Tazobactam			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Lovenox			C				Not Reported

	Insulin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055094	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055099	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Dimethicone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055100	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Glomerular Filtration Rate Decreased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Hydroxychloroquine			C				Not Reported
	Cholecalciferol			C				Not Reported
	Azithromycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Amiodarone			C				Not Reported
	Atorvastatin			C				Not Reported
	Cicatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Epoprostanol			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported

	Propofol				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055115	DIRECT	Y	DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalascent Plasma			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055119	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Transaminases Increased	Remdesivir	Y		S				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055121	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;		Gilead
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055195	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

Tacrolimus	C	Not Reported
Aspirin	C	Not Reported
Benzonatate	C	Not Reported
Dexamethasone	C	Not Reported
Enoxaparin	C	Not Reported
Famotidine	C	Not Reported
Mycophenolate	C	Not Reported
Nifedipine Xl	C	Not Reported
Bld-2660/Placebo	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055197	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055237	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484419		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055242	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484409		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Death; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055247	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Gilead
	Tocilizumab 800 Mg Iv			C				Not Reported
	Cholecalciferol			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc			C				Not Reported
	Dexamethasone 6 Mg Iv Daily			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cefepime			C				Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Budesonide			C				Not Reported
	Carvedilol			C				Not Reported
	Enoxaparin			C				Not Reported
	Finasteride			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055254	DIRECT	Y	OT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantopraxole			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055312	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484440		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Bid		Gilead
	Plasma			C		Unk		Not Reported

	Amlodipine	C	Unk	Not Reported
	Ascorbic Acid	C	Unk	Not Reported
	Dexamethasone	C	Unk	Not Reported
	Hydroxychloroquine	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Meropenem	C	Unk	Not Reported
	Vancomycin	C	Unk	Not Reported
	Zinc Sulfate	C	Unk	Not Reported
	Methylprednisolone	C	Unk	Not Reported
	Lantus	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055323	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484424		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Death; Enterobacter Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Actemra			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055324	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0484475		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Oxygen			C				Not Reported
	Plasma			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported

			Enoxaparin		C		Unk			Not Reported
			Lasix [Furosemide]		C		20 Mg, Bid			Not Reported
			Lasix [Furosemide]		C		40 Mg, Once			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18055403	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484435		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Hepatic Enzyme Increased; Hypoxia; Leukocytosis; Pneumonia Aspiration	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydroxychloroquine			C		400 Mg		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Plasma			C		Unk		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	1250 Mg		Not Reported
	Zosyn			C	Intravenous (not otherwise specified)	3.375 G, Q8h		Not Reported
	Levetiracetam			C	Intravenous (not otherwise specified)	500 Mg, Bid		Not Reported
	Amlodipine			C	Oral	5 Mg, Qd		Not Reported
	Aspirin 81			C	Oral	81 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	80 Mg, Qd		Not Reported
	Donepezil			C	Oral	10 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	100 Mg, Bid		Not Reported
	Enoxaparin			C	Subcutaneous	90 Mg, Bid		Not Reported

Fluoxetine	C	Oral	20 Mg, Once		Not Reported
Metoprolol	C	Oral	25 Mg, Bid		Not Reported
Tamsulosin	C	Oral	0.4 Mg, Qd		Not Reported
Epinephrine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056373	NON-EXPEDITED		DE, OT	US-SA-2020SA189495			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subdural Haemorrhage	Plavix			S	Unknown			Sanofi
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Heparin (Salt Not Specified)			S	Unknown			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056545	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484152		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Blood Creatinine Increased; Inflammatory Marker Increased; Liver Function Test Increased; Pneumonia Staphylococcal	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Carbamazepine			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Meropenem			C		Unk		Not Reported

	Midazolam	C	Unk	Not Reported
	Propofol	C	Unk	Not Reported
	Risperidone	C	Unk	Not Reported
	Tocilizumab	C	Unk	Not Reported
	Vancomycin	C	Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unk	Not Reported
	Zinc Sulfate	C	Unk	Not Reported
	Clonazepam	C		Not Reported
	Metformin	C		Not Reported
	Metoprolol Tartrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056597	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484192		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C	Subcutaneous	30 Mg		Not Reported
	Famotidine			C	Oral	20 Mg		Not Reported
	Culturelle			C	Oral	1 Dosage Form, Qd		Not Reported
	Vitamin C Acid			C	Oral	1 G, Qd		Not Reported
	Zinc Sulfate			C	Oral	220 Mg, Qd		Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056841	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484422		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Death; Diarrhoea; Drug Withdrawal	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Bid		Gilead

Syndrome; Nausea; Oxygen Saturation Decreased; Pulseless Electrical Activity; Vomiting	Enoxaparin	C		Unk		Not Reported
	Oxygen	C	Nasal	12 L High Flownasal Cannula		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18056972	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484177		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Pneumonia Pseudomonal; Systemic Candida	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057110	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484418		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Laboratory Test Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057123	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484429		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported

	Docusate	C	Unk		Not Reported
	Enoxaparin	C	Unk		Not Reported
	Lamotrigine	C			Not Reported
	Lithium	C			Not Reported
	Pantoprazole	C	Unk		Not Reported
	Pramipexole	C			Not Reported
	Senna	C	Unk		Not Reported
	Trazodone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057147	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484437		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057167	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484479		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Apixaban			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Atorvastatin			C				Not Reported
	Benzonatate			C		Unk		Not Reported
	Calcitriol			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Chlorhexidine			C		Unk		Not Reported

Clopidogrel	C			Not Reported
Clotrimazole	C		Unk	Not Reported
Dexamethasone	C		Unk	Not Reported
Diphenhydramine	C		Unk	Not Reported
Epoetin Alfa Epbx	C		Unk	Not Reported
Fluconazole	C		Unk	Not Reported
Furosemide	C			Not Reported
Insulin Aspart	C		Unk	Not Reported
Insulin Detemir	C		Unk	Not Reported
Insulin Regular [Insulin Porcine]	C		Unk	Not Reported
Isosorbide Mononitrate	C			Not Reported
Melatonin	C		Unk	Not Reported
Metolazone	C			Not Reported
Metoprolol Succinate	C			Not Reported
Midodrine	C			Not Reported
Mupirocin	C		Unk	Not Reported
Norepinephrine	C		Unk	Not Reported
Ondansetron	C		Unk	Not Reported
Pantoprazole	C			Not Reported
Propafenone	C			Not Reported
Sevelamer Carbonate	C		Unk	Not Reported
Terazosin	C			Not Reported
Trazodone	C			Not Reported
Vancomycin	C		Unk	Not Reported
Venlafaxine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18057283	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484715		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not	100 Mg, Qd		Gilead

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058379	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058380	DIRECT	Y	LT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058418	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058424	DIRECT	Y				22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Infusion Related Reaction; Oxygen	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead

Saturation Decreased;
Pyrexia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058427	DIRECT	Y	DE, LT			91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once - Loading Dose;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058431	DIRECT	Y	HO			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead
	Atorvastatin 40 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058438	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Hypotension; Hypoxia; Mental Status Changes; Oxygen Saturation Decreased	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone 6 Mg			C				Not Reported
	Combivent			C				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported
	Ceftriaxone 1 Gm Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058451	DIRECT	Y				56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Remdesivir	Y	S	Intravenous bolus	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058454	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058458	DIRECT	Y				50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Ketamine			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058463	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Levofloxacin			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058472	DIRECT	Y				45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058478	DIRECT	Y				86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Drug Administration Rate; Product Preparation Issue	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058482	DIRECT	Y				82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058488	DIRECT	Y	DE			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Paralysis; Respiratory Failure	Remdesivir	S	Intravenous bolus	Gilead
	Cefepime 2 Gm Iv	C		Not Reported
	Dexamethasone 2 Mg	C		Not Reported
	Famotidine 20 Mg	C		Not Reported
	Metronidazole 500 Mg	C		Not Reported
	Vancomycin Iv	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058493	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Macular; Rash Maculo-Papular	Remdesivir			S	Intravenous drip			Gilead
	Ciprofloxacin			S	Intravenous drip			Not Reported
	Senna 8.6mg			C				Not Reported
	Divalproex 500mg Dr			C				Not Reported
	Docusate Sodium 250mg			C				Not Reported
	Atorvastatin 10mg			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Pantoprazole 20mg Tablet			C				Not Reported
	Haloperidol 5mg Tablet			C				Not Reported
	Acetaminophen 500mg Tablet			C				Not Reported
	Enoxaparin 40mg Sc			C				Not Reported
	Metoprolol 50mg Ir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058500	DIRECT	Y	HO			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058507	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Enzyme Increased	Remdesivir	S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir	S	Intravenous drip			Gilead
	Atorvastatin 40 Mg Oral Daily	C				Not Reported
	Ascorbic Acid 3000 Mg Oral Bid	C				Not Reported
	Cholecalciferol 25 Mcg Oral Daily	C				Not Reported
	Dexamethasone 6 Mg Daily Iv	C				Not Reported
	Furosemide 40 Mg Iv Bid	C				Not Reported
	Zinc 220 Mg Daily Oral	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058533	DIRECT	Y				47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2020	18058540	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	17914969	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0473383		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; General Physical Health Deterioration; Pneumothorax; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C	Intravenous (not otherwise specified)	1500 Mcg		Not Reported

Atorvastatin	C	Oral	10 Mg	Not Reported
Aztreonam	C	Intravenous bolus	2 G	Not Reported
Bisacodyl	C	Oral	5 Mg	Not Reported
Buspirone	C	Oral	10 Mg	Not Reported
Carbidopa-Levodopa-B	C	Oral	25 Mg - 100 Mg	Not Reported
Celebrex	C	Oral	100 Mg	Not Reported
Clonazepam	C	Oral	0.5 Mg	Not Reported
Digoxin	C	Oral	62.5 Mcg	Not Reported
Depakote	C			Not Reported
Lovenox Hp	C	Subcutaneous	60 Mg	Not Reported
Fentanyl 3 Day Hmt	C		200 Mcg	Not Reported
Guaifenesin	C	Oral	600 Mg	Not Reported
Metoprolol	C			Not Reported
Propofol	C	Intravenous (not otherwise specified)	10 Mcg	Not Reported
Risperidone	C	Oral	0.5 Mg	Not Reported
Oxygen	C			Not Reported
Albuterol [Salbutamol]	C	Respiratory (inhalation)	360 Mcg	Not Reported
Cetirizine	C	Oral	10 Mg	Not Reported
Peridex [Chlorhexidine Gluconate]	C	Oral	15 Ml	Not Reported
Cyanocobalamin	C	Oral	500 Mcg	Not Reported
Decadron [Dexamethasone Acetate]	C	Intravenous (not otherwise specified)	4 Mg	Not Reported
Senokot S	C	Oral	1 Dosage Form	Not Reported
Pepcid [Famotidine]	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
Fluticasone	C	Respiratory (inhalation)	220 Mcg	Not Reported
Magnesium Citrate	C		30 Ml	Not Reported
Solu-Medrol	C	Intravenous (not	30 Mg	Not Reported

			otherwise specified)		
	Midodrine	C	Oral	5 Mg	Not Reported
	Montelukast	C	Oral	10 Mg	Not Reported
	Pyridoxine	C	Oral	20 Mg	Not Reported
	Sodium Bicarbonate	C	Intravenous (not otherwise specified)	50 Meq	Not Reported
	Thiamine	C	Intravenous bolus	200 Mg	Not Reported
	Zanaflex	C	Oral	4 Mg	Not Reported
	Trazodone	C			Not Reported
	Depacon	C	Intravenous (not otherwise specified)	150 Mg	Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	750 Mg	Not Reported
	Effexor Sr	C	Oral	150 Mg	Not Reported
	Fiorinal [Acetylsalicylic Acid; Butalbital;Caffeine]	C			Not Reported
	Dexmedetomidine	C	Intravenous (not otherwise specified)	400 Mcg	Not Reported
	Epinephrine	C	Intravenous (not otherwise specified)	4 Mg	Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	15 Mg	Not Reported
	Vasopressin	C	Intravenous (not otherwise specified)	40 Units	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18000931	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0480838		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Ammonium Lactate			C	Topical	1 App		Not Reported
	Clonazepam			C	Oral	0.5 Mg, Bid		Not Reported

	Dexamethasone	C	Oral	6 Mg, Qd		Not Reported
	Divalproex Sodium	C	Oral	125 Mg, Tid		Not Reported
	Levetiracetam	C	Oral	1000 Mg		Not Reported
	Mirtazapine A	C	Oral	15 Mg		Not Reported
	Lactulose	C	Oral	40 G, Bid		Not Reported
	Melatonin	C	Oral	15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058096	EXPEDITED (15-DAY)			US-GILEAD-2020-0484800		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18058774	EXPEDITED (15-DAY)		DE, OT	GB-MYLANLABS-2020M1064915		84 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Livedo Reticularis	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Tid		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200, Stat		Mylan
	Vancomycin			S	Intravenous (not otherwise specified)	1 G, Bid		Mylan
	Dexamethasone			S	Oral	6 Mg, Qd		Mylan
	Oxygen			C		Unk		Mylan
	Allopurinol			C		Unk		Mylan
	Fexofenadine			C				Mylan
	Atorvastatin			C				Mylan
	Omeprazole			C				Mylan
	Dalteparin			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059145	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Decreased; Aspartate Aminotransferase Decreased; Hepatotoxicity	Remdesivir			S	Intravenous (not otherwise specified)		4 DAY	Gilead
	Tamsulosin 0.4 Mg Daily			C				Not Reported
	Metoprolol Succinate 25 Mg Daily			C				Not Reported
	Insulin Glargine & Lispro			C				Not Reported
	Lisinopril 5 Mg Daily			C				Not Reported
	Enoxaparin 30 Mg Q12h			C				Not Reported
	Aspirin 325 Mg Daily			C				Not Reported
	Allopurinol 300 Mg Daily			C				Not Reported
	Acetaminophen 650 Mg Q4h Prn (1 Dose Given)			C				Not Reported
	Atorvastatin 80 Mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059300	DIRECT	Y	DE			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Oxygen Saturation Decreased; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Donepizil			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Isosorbide			C				Not Reported
	Lorazepam			C				Not Reported
	Metoprolol			C				Not Reported
	Quetiapine			C				Not Reported

		Morphine			C					Not Reported
		Haloperidol			C					Not Reported
		Ondansetron			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059532	DIRECT	Y				47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059728	DIRECT	Y	HO			17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059746	DIRECT	Y				34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059811	DIRECT	Y				87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059877	DIRECT	Y				55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18059882	DIRECT	Y				75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18060296	DIRECT	Y	OT			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Norco			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18060302	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Transfusion	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported
	Levophed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061316	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484733		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Isosorbide			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Potassium			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Apixaban			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Iohexol			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061558	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484363		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Unfractionated Heparin			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported

Insulin Lispro	C	Unk	Not Reported
Linezolid	C	Unk	Not Reported
Mycophenolate	C	Unk	Not Reported
Tacrolimus	C	Unk	Not Reported
Dexmedetomidine	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Midazolam	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Sodium Bicarbonate	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18061613	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482969		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18064217	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18064224	DIRECT	Y				39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

		Trazodone			C					Not Reported
		Famotidine			C					Not Reported
		Albuterol			C					Not Reported
		Norco			C					Not Reported
		Acetaminophen			C					Not Reported
		Thiamine			C					Not Reported
		Ascorbic Acid			C					Not Reported
		Lovenox			C					Not Reported
		Dexamethasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18064231	DIRECT	Y	DE, HO, LT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Amiodarone			C				Not Reported
	Azithromycin			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Thiamine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Sodium Bicarbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18064238	DIRECT	Y	DE			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Anuria;	Remdesivir			S				Not Reported

Candida Infection;
Pneumonia Pseudomonal;
Septic Shock;
Streptococcal Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18064294	DIRECT	Y	DE, OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemodialysis; Renal Impairment	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead
	Toclizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18064343	DIRECT	Y	DE			90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Pain; Respiratory Failure; Sedation	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18064778	DIRECT	Y	RI			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Hyperhidrosis; Hypertension; Oxygen Saturation Decreased	Remdesivir 200mg			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead
	Atracurium			C				Not Reported
	Insulin Glargine			C				Not Reported
	Chlorhexidine Gluconate			C				Not Reported
	Sennosides			C				Not Reported
	Docusate			C				Not Reported
	Albuterol			C				Not Reported

		Rocuronium			C						Not Reported
		Dexamethasone Sodium Phosphate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2020	18064943	DIRECT	Y	RI			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir 100mg			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead
	Rocephin			C				Not Reported
	Azithromycin			C				Not Reported
	Dexamethasone Sodium Phosphate			C				Not Reported
	Fentanyl			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17971419	EXPEDITED (15-DAY)		DE, HO, LT	FR-AUROBINDO-AUR-APL-2020-031896		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective For Unapproved Indication; Off Label Use	Levofloxacin			S	Unknown	Unk		Aurobindo
	Levofloxacin			S				Aurobindo
	Meropenem			S	Unknown	Unk		Aurobindo
	Meropenem			S				Aurobindo
	Voriconazole			S	Unknown	Unk		Aurobindo
	Colimycine [Colistin Sulfate]			S	Unknown	Unk		Not Reported
	Colimycine [Colistin Sulfate]			S				Not Reported

				Isavuconazonium Sulfate	S	Unknown	Unk		Not Reported
				Isavuconazonium Sulfate	S				Not Reported
				Tigecycline	S	Unknown	Unk		Not Reported
				Tigecycline	S				Not Reported
				Remdesivir	S	Intravenous drip	200 Milligram (Loading Dose)		Not Reported
				Remdesivir	S	Unknown	Unk		Not Reported
				Remdesivir	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	17996635	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478717		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Dexamethasone			C	Oral	6 Mg, Qd		Not Reported
	Plasma			C		Unk		Not Reported
	Enoxaparin			C		40 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Q4hr, As Needed		Not Reported
	Omeprazole			C				Not Reported
	Tamsulosin			C	Oral	0.4 Mg, Qd		Not Reported
	Pantoprazole			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062555	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485076		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin	C		Unk		Not Reported
	Ceftriaxone	C		Unk		Not Reported
	Dexamethasone	C		Unk		Not Reported
	Enoxaparin	C		Unk		Not Reported
	Tocilizumab	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18062589	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485054		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous drip	100 Mg Daily		Gilead
	Rocephin [Ceftriaxone]			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Zosyn			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065426	DIRECT	Y	HO			1 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Antidiuretic Hormone Secretion	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065496	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Heart Rate Decreased	Remdesivir			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065586	DIRECT	Y				20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Trazadone 25 Mg			C				Not Reported
	Dexamethasone 6 Mg			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065608	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065617	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065620	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Rocephin			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065740	DIRECT	Y	DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Remdesivir			S				Not Reported
	Vancomycin			C				Not Reported
	Apixaban			C				Not Reported
	Cefepime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18065824	DIRECT	Y	OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Erythema; Infusion Site Extravasation; Infusion Site Swelling	Remdesivir	Y		S	Intravenous drip			Gilead
	Thiamine 100 Mg			C				Not Reported
	Terazosin 1 Mg			C				Not Reported
	Olanzapine 2.5 Mg In Am And 5mg In Pm			C				Not Reported
	Nystatin Powder			C				Not Reported
	Mirtazapine 15 Mg			C				Not Reported
	Insulin Lispro			C				Not Reported
	Folic Acid 1mg			C				Not Reported
	Enoxaparin 40 Mg Qc			C				Not Reported
	Donepazil 10 Mg Daily			C				Not Reported
	Dexamethasone 6mg Oral Tab			C				Not Reported
	Clonidine 0.1 Mg Every 12h			C				Not Reported
	Citalopram 20mg			C				Not Reported
	Cholecalciferol 1000 Units Po			C				Not Reported
	Bupropion Xl 300mg			C				Not Reported
	Atorvastatin 20mg			C				Not Reported
	Aspirin Ec 81mg			C				Not Reported
	Alprazolam 0.5mg Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066173	DIRECT	Y	DE			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypoxia; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip	Other Frequency:Once Then 100mg Da;		Gilead
	Ascorbic Acid			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Lorazepam			C				Not Reported
	Meropenem			C				Not Reported
	Doxycycline			C				Not Reported
	Methylprednisolone			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066227	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypovolaemic Shock	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Amiodarone			C				Not Reported
	Amlodipine			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Carvedilol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Lansoprazole			C				Not Reported
	Vasopressin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Epinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066233	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066239	DIRECT	Y				60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Dexamethasone			C				Not Reported
	Ascorbic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066243	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulse Absent; Respiratory Arrest; Sars-Cov-2 Test Positive	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066285	DIRECT	Y				71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

	Zinc Sulfate			C						Not Reported
	Ascorbic Acid			C						Not Reported
	Enoxaparin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066287	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Pravastatin			C				Not Reported
	Lisinopril			C				Not Reported
	Levothyroxine			C				Not Reported
	Bisoprolol			C				Not Reported
	Aspirin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066290	DIRECT	Y				66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Montelukast 10 Mg			C				Not Reported
	Lisinopril			C				Not Reported
	Combivent Respimat			C				Not Reported
	Insulin Lispro			C				Not Reported
	Gabapentin 300 Mg			C				Not Reported
	Enoxaparin			C				Not Reported
	Duloxetine 60 Mg			C				Not Reported
	Dexamethasone 6 Mg			C				Not Reported
	Symbicort			C				Not Reported

		Atorvastatin			C						Not Reported
		Aspirin Chewable			C						Not Reported
		Amlodipine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066297	DIRECT	Y	DE			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Breath Sounds Absent; Pulse Absent	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066300	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardiac Arrest; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Tocilizumab			C				Not Reported
	Sodium Bicarbonate Infusion			C				Not Reported
	Vasopressin			C				Not Reported
	Phenylephrine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Amiodarone			C				Not Reported
	Azithromycin			C				Not Reported
	Epinephrine			C				Not Reported
	Albumin 25%			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Heparin Sq			C				Not Reported
	Enoxaparin Treatment Dosing			C				Not Reported
	Enoxaparin Ppx Dosing			C				Not Reported
	Famotidine			C				Not Reported

	Insulin			C						Not Reported
	Furosemide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18066305	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Throat Tightness	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Clonidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Hydralazine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Levothyroxine			C				Not Reported
	Metoprolol Succinate Xl			C				Not Reported
	Oxybutynin			C				Not Reported
	Pantoprazole Ec			C				Not Reported
	Polyethylene Gylcol			C				Not Reported
	Rosuvastatin			C				Not Reported
	Senna			C				Not Reported
	Tamsulosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18068101	EXPEDITED (15-DAY)			US-GILEAD-2020-0484476			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18068870	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485506		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18070936	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Lyophilized Powder	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Albuterol/Ipratropium			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Iohexol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18070943	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Arrest	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Methylprednisolone 60 Mg Iv Q12h			C				Not Reported
	Dexamethasone 6mg Po Daily			C				Not Reported
	Enoxpararin 1 Mg/Kg Sc Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18070950	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir	S	Intravenous bolus	4 DAY	Gilead
	Metoprolol 12.5 Mg	C			Not Reported
	Heparin 500 Sq	C			Not Reported
	Doxazosin 2 Mg	C			Not Reported
	Dexamethasone 6 Mg	C			Not Reported
	Clopidogrel	C			Not Reported
	Aspirin 81	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18070955	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported
	Etomidate			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Lorazapam			C				Not Reported
	Midazolam			C				Not Reported
	Fentanyl			C				Not Reported
	Lansoprazole			C				Not Reported
	Methylprednisolone			C				Not Reported
	Insulin			C				Not Reported
	Norepinephrine			C				Not Reported
	Ascorbic Acid (Iv)			C				Not Reported
	Enoxaparin			C				Not Reported
	Carvedilol			C				Not Reported
	Tocilizumab			C				Not Reported
	Amlodipine			C				Not Reported
	Losartan			C				Not Reported
	Aspirin			C				Not Reported
	Furosemide			C				Not Reported
	Albuterol			C				Not Reported
	Metolazone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18070989	DIRECT	Y				51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir	S	Intravenous drip	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18071052	DIRECT	Y	DE			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Decreased; Blood Chloride Increased; Blood Creatinine Increased; Blood Glucose Increased; Blood Magnesium Increased; Blood Phosphorus Increased; Blood Potassium Increased; Blood Urea Increased; Carbon Dioxide Decreased; Cardiac Arrest; Glomerular Filtration Rate Increased; Haematocrit Decreased; Red Blood Cell Count Decreased; Sars-Cov-2 Test Positive; White Blood Cell Count Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma X 2 Units At Other Hosp			C				Not Reported
	Tocilizumab 800 Mg X 1 At Other Hosp			C				Not Reported
	Amiodarone 200 Mg Po Q12hr			C				Not Reported
	Azithromycin 500 Mg Feed Tube Daily			C				Not Reported
	Dexamethasone 10 Mg Iv Once Daily			C				Not Reported
	Dexamethasone 6 Mg Iv Daily			C				Not Reported
	Enoxaparin 100 Mg Sq Q12hrs			C				Not Reported
	Famotodine 20 Mg Iv Bid			C				Not Reported
	Lantus Up To 20 Untis Sq Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18071078	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua)			S	Intravenous (not otherwise specified)			Gilead
	Dexmedetomidine In Ns 400 Mcg/100 Ml (4 Mcg/Ml) Iv Premix (Precedex In			C				Not Reported
	Fentanyl (Pf) In Ns 10 Mcg/Ml Iv Soln			C				Not Reported

		Heparin (Porcine) In D5w 25,000 Unit/250 Ml(100 Unit/Ml) Iv Premix		C					Not Reported
		Insulin Regular Human Sliding Scale Inj (Humulin R/Novolin R)		C					Not Reported
		Ipratropium 17 Mcg/Actuation Mdi 2 Puff (Atrovent Hfa)		C					Not Reported
		Melatonin Rap Dis Tablet 10 Mg		C					Not Reported
		Metronidazole In Nacl Iv Premix 500 Mg (Flagyl)		C					Not Reported
		Midazolam In Ns 1 Mg/Ml Iv Soln		C					Not Reported
		Ascorbic Acid Ivpb 1,500 Mg		C					Not Reported
		Phenylephrine 100 Mg In Sodium Chloride 0.9% 250 Ml Iv Soln		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18071081	DIRECT	Y	DE			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tylenol			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Nimbex			C				Not Reported
	Ryanodex			C				Not Reported
	Lovenox			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18071087	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Glucose Increased; Blood Urea Increased; Glomerular	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 5 Mg Iv Once Daily			C				Not Reported

Filtration Rate Decreased	Carvedilol 3.125 Mg Po Bid			C					Not Reported
	Valproate Sodium 500 Mg Po Hs			C					Not Reported
	Ticagrelor 90 Mg Po Q12hr			C					Not Reported
	Thiamine 100 Mg Po Once Daily			C					Not Reported
	Spironolactone 25 Mg Po Daily			C					Not Reported
	Entresto 24/26 Po Bid			C					Not Reported
	Pantoprazole 40 Mg Po Once Daily			C					Not Reported
	Megestrol 400 Mg Po Bid			C					Not Reported
	Furosemide 40 Mg Iv Once Daily			C					Not Reported
	Fluconazole 100 Mg Po Once Daily			C					Not Reported
	Ezetimibe 10 Mg Po Once Daily			C					Not Reported
	Enoxaparin 80 Mg Sq Q12hr			C					Not Reported
	Atorvastatin 80 Mg Po Hs			C					Not Reported
	Asa 81 Mg Po Once Daily			C					Not Reported
	Albuterol Mdi Rt Bid			C					Not Reported
	Clinimix E 2.75%-5%			C					Not Reported
	Tpn Custom			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18071657	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S				Not Reported
	Cyclosporine			C				Not Reported
	Decadron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2020	18073245	DIRECT	Y	OT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bacterial	Remdesivir 100mg/Ml			S	Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Fluticasone			C				Not Reported

Infection; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Disease Progression; Procalcitonin Increased; Respiratory Failure; White Blood Cell Count Increased	Budesonide Neb			C					Not Reported
	Vitamin D			C					Not Reported
	Zinc Sulfate			C					Not Reported
	Methimazole			C					Not Reported
	Ceftriaxone			C					Not Reported
	Vancomycin			C					Not Reported
	Acetyicysteine			C					Not Reported
	Omnipaque			C					Not Reported
	Methyprednisolone			C					Not Reported
	Thiamin			C					Not Reported
	Enoxaparin			C					Not Reported
	Famotidine			C					Not Reported
	Atorvastatin			C					Not Reported
	Avithromycin			C					Not Reported
	Aspirin			C					Not Reported
	Melatonin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18071093	DIRECT	Y	OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol-Ipratropium			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18071098	DIRECT	Y	OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once As Ld.;		Gilead
	Acetaminophen 650 Mg Po Q6h Prn			C				Not Reported
	Albuterol 2 Puff Q4h			C				Not Reported
	Ascorbic Acid 1000 Mg Po Daily			C				Not Reported
	Clozapine 100 Mg Po Bid			C				Not Reported
	Robitussin Ac 10 Ml Po Q8h Prn			C				Not Reported

	Cough								
	Dexamethasone 6 Mg Iv Bid			C					Not Reported
	Duloxetine 30 Mg Po Daily			C					Not Reported
	Enoxaparin 40 Mg Sc Bid			C					Not Reported
	Famotidine 20 Mg Po Bid			C					Not Reported
	Labetalol 100 Mg Po Bid			C					Not Reported
	Lisinopril 10 Mg Po Daily			C					Not Reported
	Spironolactone 25 Mg Po Daily			C					Not Reported
	Thiamine Mononitrate 100 Mg Po Daily			C					Not Reported
	Topiramate 100 Mg Po Bedtime			C					Not Reported
	Zinc Sulfate 220 Mg Po Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18071103	DIRECT	Y	OT			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Alfuzosin			C				Not Reported
	Amlodipine			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydralazine			C				Not Reported
	Insulin			C				Not Reported
	Melatonin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Sennosides			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18071109	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Furosemide			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Epoprostenol			C				Not Reported
	Enoxaparin			C				Not Reported

		Famotidine			C					Not Reported
		Ketamine			C					Not Reported
		Ceftriaxone			C					Not Reported
		Azithromycin			C					Not Reported
		Levofloxacin			C					Not Reported
		Norepinephrine			C					Not Reported
		Methylprednisolone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18071115	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18071156	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2020	18071160	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guafenisin			C				Not Reported
	Ketorolac			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18071165	DIRECT	Y	OT			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2020	18072868	DIRECT	Y	DE			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulse Absent; Respiratory Arrest; Subcutaneous Emphysema	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Other Route:Iv		Gilead
	Acetaminophen			C	Oral			Not Reported
	Albuterol			C		Other Dose:2 Puffs;Other Frequency:Q6-8 Hr;		Not Reported
	Ascorbic Acid (Vitamin C)			C	Oral			Not Reported
	Atorvastatin			C	Oral			Not Reported
	Azithromycin			C		Other Route:Iv		Not Reported
	Azithromycin			C	Oral			Not Reported
	Cefazolin			C		Other Route:Iv		Not Reported
	Cefepime			C		Other Route:Iv		Not Reported
	Chlorhexidine			C	Oral			Not Reported
	Cholecalciferol (Vitamin D3)			C	Oral	Other Frequency:Once Or Bid;		Not Reported
	Dexamethasone			S		Other Frequency:Q 12-24 Hr;Other Route:Iv		Not Reported
	Donepezil			C	Oral			Not Reported

Enoxaprin	S	Subcutaneous	Other Dose:40-60 Mg; Other Frequency:Q 12-24 Hr;	Not Reported
Fentanyl	C		Other Frequency: Continuous;Other Route:Iv	Not Reported
Furosemide	C		Other Frequency:X 3 Doses;Other Route:Iv	Not Reported
Guaifenesin	C	Oral		Not Reported
Hydrocodone- Acetaminophen	C	Oral	Other Frequency:Q 6-12 Hr;	Not Reported
Insulin Aspart	C	Subcutaneous	Other Dose:0-10 Units; Other Frequency:Ac & Hs Prn;	Not Reported
Insulin Detemir	C	Subcutaneous	Other Dose:8-25 Units;	Not Reported
Insulin, Regular	C	Subcutaneous	Other Dose:0-10 Units; Other Frequency:Q 4 Hr Prn;	Not Reported
Losartan	C	Oral		Not Reported
Meclizine	C	Oral		Not Reported
Melatonin	C	Oral		Not Reported
Methylprednisolone Sodium Succinate	C		Other Dose:40-125 Mg; Other Route:Iv	Not Reported
Mupirocin	C	Nasal		Not Reported
Norepinephrine	C		Other Dose:0.02-0.16 Mcg/Kg/M;Other Frequency:Continuous; Other Route:Iv	Not Reported
Ondansetron	C		Other Route:Iv	Not Reported
Propofol	C		Other Frequency: Continuous;Other Route:Iv	Not Reported
Senna - Docusate 8.5 - 50	C	Oral		Not Reported
Vancomycin	C		Other Frequency: Intermittent Dosin;Other Route:Iv	Not Reported

		Zinc Sulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17868186	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469280		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Tylenol			C				Not Reported
	Zosyn			C		Unk		Not Reported
	Doxycycline			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Albumin			C		Unk		Not Reported
	Amino Acids Nos			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Calcium & Vitamin D [Calcium; Colecalciferol]			C		Unk		Not Reported
	Fat Emulsions			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Haloperidol			C		Unk		Not Reported
	Insulin Regular Hm			C		Unk		Not Reported
	Levalbuterol [Levosalbutamol]			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Multivitamin And Mineral			C		Unk		Not Reported
	Ns			C		Unk		Not Reported

	Potassium Chloride	C	Unk		Not Reported
	Sodium Chloride	C	Unk		Not Reported
	Sodium Phosphate	C	Unk		Not Reported
	Tpn [Amino Acids Nos; Carbohydrates Nos;Minerals Nos;Vitamins Nos]	C	Unk		Not Reported
	Zinc Sulfate	C	Unk		Not Reported
	Kinevac	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17882674	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0469816		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	200mg X 1, 100mg X 1		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Melatonin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Morphine			C				Not Reported
	Pantoprazole			C				Not Reported
	Insulin			C				Not Reported
	Zinc			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Sucralfate			C				Not Reported
	Decadron [Dexamethasone]			C		Unk		Not Reported
	Decadron [Dexamethasone]			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	17882697	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469673		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Covid-19 Pneumonia; Hypovolaemia; Pneumonia Staphylococcal; Renal Tubular Necrosis; Sepsis; Septic Shock	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Unk	Gilead
	Norepinephrine	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enoxaparin	C	Subcutaneous	30 Mg	Not Reported
	Etomidate	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
	Famotidine	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
	Furosemide	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
	Furosemide	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
	Heparin	C	Subcutaneous	7500 Units	Not Reported
	Lorazepam	C	Oral	4 Mg	Not Reported
	Metoclopramide	C	Intravenous (not otherwise specified)	10 Mg	Not Reported
	Vecuronium	C	Intravenous (not otherwise specified)	10 Mg	Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Cefazolin	C	Intravenous (not otherwise specified)	2 G	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported
	Dexmedetomidine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Diltiazem	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Metoprolol	C	Intravenous (not otherwise specified)	2.5 Mg	Not Reported
	Propofol	C	Intravenous (not	Unk	Not Reported

				otherwise specified)			
	Vancomycin		C	Intravenous (not otherwise specified)	1750 Mg		Not Reported
	Potassium Chloride		C	Intravenous (not otherwise specified)	40 Meq		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072744	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hypersensitivity	Remdesivir Eua	Y		S				Gilead
	Insulin Nph 5 Units			C				Not Reported
	Atorvastatin 20mg			C				Not Reported
	Pantoprazole 40mg			C				Not Reported
	Aspirin 81mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072756	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072768	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072778	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072790	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Levophed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072809	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072842	DIRECT	Y	OT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Famotidine			C				Not Reported

		Gammunex			C					Not Reported
		Insulin Lispro			C					Not Reported
		Methylprednisone			C					Not Reported
		Potassium Chloride			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072846	DIRECT					76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072852	DIRECT	Y	HO			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 6 Mg Iv			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18072951	DIRECT	Y	DE, OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Slow Response To Stimuli; Tachycardia	Remdesivir 100mg/20ml			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg Injection			S	Intravenous (not otherwise specified)	Frequency Daily X 4 Days	4 DAY	Gilead
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Diltiazem			C				Not Reported
	Hydralazine			C				Not Reported
	Labetalol			C				Not Reported

		Metoprolol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18073621	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0485716		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydroxychloroquine			C				Not Reported
	Cholecalciferol			C				Not Reported
	Azithromycin			C				Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Amiodarone			C				Not Reported
	Atorvastatin			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Epoprostenol			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18074246	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485069			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Bradycardia; Fluid Overload	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Propofol			C		Unk		Not Reported
	Versed			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18076581	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486049		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Myocardial Infarction; Covid-19	Remdesivir	S	Unknown	Unk		Gilead
	Acetaminophen	C				Not Reported
	Etomidate	C				Not Reported
	Propofol	C				Not Reported
	Rocuronium	C				Not Reported
	Lorazepam	C				Not Reported
	Midazolam	C				Not Reported
	Fentanyl	C				Not Reported
	Lansoprazole	C				Not Reported
	Methylprednisolone	C				Not Reported
	Insulin	C				Not Reported
	Norepinephrine	C				Not Reported
	Ascorbic Acid	C				Not Reported
	Enoxaparin	C				Not Reported
	Carvedilol	C				Not Reported
	Tocilizumab	C				Not Reported
	Amlodipine	C				Not Reported
	Losartan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18077503	EXPEDITED (15-DAY)			US-GILEAD-2020-0479527		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error; Product Temperature Excursion Issue	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18077545	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0486092		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Septic Shock	Remdesivir			S	Unknown	Completed An Extended 10-Day Course In 2020		Gilead
	Dexamethasone			C		Completed A 10 Day Course In 2020		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18077728	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0485681		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078185	DIRECT	Y	OT			26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Therapy Cessation	Remdesivir			S			3 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078194	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;		Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078205	DIRECT	Y	HO, LT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Losartan			C				Not Reported

	Sotalol			C				Not Reported
	Metoclopramide			C				Not Reported
	Tocilizumab			C				Not Reported
	Ambien			C				Not Reported
	Levothyroxine			C				Not Reported
	Fiorcet			C				Not Reported
	Solu-Medrol			C				Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Atorvastatin			C				Not Reported
	Robitussin Ac			C				Not Reported
	Levemir			C				Not Reported
	Albuterol			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Oxybutynin			C				Not Reported
	Citalopram			C				Not Reported
	Lovenox			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078218	DIRECT	Y	HO, LT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Sodium Chloride			C				Not Reported
	Azithromycin			C				Not Reported
	Lovenox			C				Not Reported
	Cefepime			C				Not Reported
	Solu-Medrol			C				Not Reported
	Levemir			C				Not Reported
	Novolog			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078228	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Arrest; Condition Aggravated; Septic Shock	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethason			C				Not Reported
	Cisatracurium			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078249	DIRECT	Y	DE			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Anxiety; Bilevel Positive Airway Pressure; Respiratory Failure; Unresponsive To Stimuli	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078277	DIRECT	Y	HO			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir	Y		S	Intravenous bolus			Gilead
	Iv Vancomycin			C				Not Reported
	Iv Piperacillin-Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078287	DIRECT	Y	OT			91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Renal Failure	Remdesivir	Y	S	Intravenous drip	Gilead
	Dexamethamethsone		C		Not Reported
	Lovenox		C		Not Reported
	Glimepiride		C		Not Reported
	Irbesartan		C		Not Reported
	Ivermectin		C		Not Reported
	Azithromycin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078366	DIRECT	Y				9 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Preparation Issue	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078376	DIRECT	Y				89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip		3 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078388	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Lovenox			C				Not Reported
	Decadron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078397	DIRECT	Y				83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip		3 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078408	DIRECT	Y	HO			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Azithromycin 500mg Iv Daily			C				Not Reported
	Furosemide 40mg Iv Twice Daily			C				Not Reported
	Acetaminophen As Needed			C				Not Reported
	Albuterol/Ipratropium Neb Four Times Daily			C				Not Reported
	Ascorbic Acid 500mg Oral Three Times Daily			C				Not Reported
	Budesonide Neb			C				Not Reported
	Ceftriaxone 2gm Ivpb Daily			C				Not Reported
	Cholecalciferol 1,000units Daily			C				Not Reported
	Doxycycline 100mg Ivpb Twice Daily			C				Not Reported
	Enoxaparin 40mg Sub Q Daily			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Methylprednisolone 60mg Ivp Q6h			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Pantoprazole 40mg Iv Daily			C				Not Reported
	Thiamine 200mg Iv Daily			C				Not Reported
	Vecuronium Infusion			C				Not Reported

	Zinc Sulfate 220mg Oral Twice Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078420	DIRECT	Y				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Erythema; Infusion Site Swelling; Injection Site Extravasation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078433	DIRECT	Y	HO			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen As Needed			C				Not Reported
	Albuterol/Ipratropium Neb 4 Times Daily			C				Not Reported
	Amlodipine 10mg At Bedtime			C				Not Reported
	Ascorbic Acid 500mg Tablet Twice Daily			C				Not Reported
	Aspirin 81mg Daily			C				Not Reported
	Atenolol 50mg Tablet Daily			C				Not Reported
	Atorvastatin 40mg Daily			C				Not Reported
	Budesonide 0.5mg Neb Twice Daily			C				Not Reported
	Clopidogrel 75mg Tablet Daily			C				Not Reported
	Enoxaparin 40mg Sub Q Daily			C				Not Reported
	Famotidine 20mg Tablet Twice Daily			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Furosemide 40mg Iv Twice Daily			C				Not Reported
	Lactobacillus 1 Capsule Daily			C				Not Reported
	Linezolid 600mg Iv Q12h			C				Not Reported
	Meropenem 1g Iv Q12h			C				Not Reported

		Methylprednisolone 40mg Iv Q6h			C					Not Reported
		Midazolam Infusion			C					Not Reported
		Thiamine 200mg Iv Twice Daily			C					Not Reported
		Zinc Sulfate 220mg Po Twice Dialy			C					Not Reported
		Norepinephrine Infusion			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078441	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Apixaban 5mg Bid			C				Not Reported
	Buproprion 50mg Tid			C				Not Reported
	Duloxetine 30mg Daily			C				Not Reported
	Apripirazole 5mg Bid			C				Not Reported
	Insulin Glargine 15units Hs			C				Not Reported
	Levothyroxine 100mcg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078450	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500 My Po Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Q24h			C				Not Reported
	Enoxaparin 40 Mg Sq Q12h			C				Not Reported
	Furosime 20 Mg Ivpush Daily			C				Not Reported
	Methylprednisolone 20 Mg Iv Q6h			C				Not Reported
	Prednisone 40 Mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078470	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Injury	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Fentyl Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported
	Rocuronium Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078474	DIRECT	Y	OT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078481	DIRECT		OT			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078538	DIRECT	Y	OT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Azithromycin 250mg Daily			C				Not Reported
	Famotidine 20mg Bid			C				Not Reported
	Ceftriaxone 1gm Q 24h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18078545	DIRECT	Y				88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Remdesivir			S	Intravenous drip			Gilead
	Rivaroxaban			S	Oral		1 YR	Janssen
	Remdesivir			C				Not Reported
	Rivaroxaban			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18079270	DIRECT	Y	DE			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoeic Attack; Brain Death; Confusional State; Fatigue; Lethargy; Myasthenia Gravis Crisis; Pulse Absent	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Alprazolam			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Hydrocortisone Sodium Succinate			C				Not Reported
	Mupirocin			C				Not Reported
	Mycophenolate			C				Not Reported
	Norepinephrine			C				Not Reported
	Vitamin D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18079401	DIRECT	Y	DE			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Condition Aggravated; Oxygen Saturation Decreased	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not			Gilead

					otherwise specified)				
	Acetaminophen			C					Not Reported
	Albuterol			C					Not Reported
	Alprazolam			C					Not Reported
	Amlodipine			C					Not Reported
	Ascorbic Acid (Vitamin C)			C					Not Reported
	Atorvastatin			C					Not Reported
	Chlorhexidine			C					Not Reported
	Cholecciferol (Vitamin D3)			C					Not Reported
	Clonidine			C					Not Reported
	Dexamethasone			C					Not Reported
	Diphenhydramine			C					Not Reported
	Enoxaparin			C					Not Reported
	Famotidine			C					Not Reported
	Gabapentin			C					Not Reported
	Hydralazine			C					Not Reported
	Levofloxacin			C					Not Reported
	Lorazepam			C					Not Reported
	Mupirocin			C					Not Reported
	Ondansetron			C					Not Reported
	Patiromer Calcium Sorbitex			C					Not Reported
	Sodium Bicarbonate			C					Not Reported
	Sodium Bicarbonate In Dextrose 5%			C					Not Reported
	Sucralfate			C					Not Reported
	Timolol Maleate 0.5%			C					Not Reported
	Zinc Sulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18079480	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir Solution 100 Mg Vial	Y		S	Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Remdesivir Solution 100 Mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Bupropion			C				Not Reported
	Chlorhexidine			C				Not Reported
	Citalopram			C				Not Reported

	Dexamethasone	C	Not Reported
	Diphenhydramine	C	Not Reported
	Enoxaparin	C	Not Reported
	Furosemide	C	Not Reported
	Insulin, Regular	C	Not Reported
	Melatonin	C	Not Reported
	Mupirocin	C	Not Reported
	Nifedipine	C	Not Reported
	Quetiapine	C	Not Reported
	Tamsulosin	C	Not Reported
	Zolpidem	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2020	18085061	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Abnormal	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17931173	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474765		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Death; Pulseless Electrical Activity; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Lorazepam			C	Intravenous (not otherwise specified)	1.5 Mg		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Metoprolol Tartrate			C	Intravenous (not	5 Mg		Not Reported

			otherwise specified)		
	Potassium Chloride	C		Unk	Not Reported
	Sodium Chloride 0.9%	C		Unk	Not Reported
	Hydralazine	C	Intravenous (not otherwise specified)	10 Mg	Not Reported
	Morphine	C	Intravenous (not otherwise specified)	4 Mg	Not Reported
	Vecuronium	C		Unk	Not Reported
	Epinephrine	C		Unk	Not Reported
	Phenylephrine	C		Unk	Not Reported
	Propofol	C		Unk	Not Reported
	Sodium Bicarbonate	C		100 Meq	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported
	Pantoprazole	C	Intravenous (not otherwise specified)	40 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	17992213	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0479521		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lisinopril			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)			Not Reported
	Cisatracurium			C				Not Reported

		Sodium Bicarbonate			C					Not Reported
		Epinephrine			C					Not Reported
		Epoprostenol			C					Not Reported
		Hydromorphone			C					Not Reported
		Midazolam			C					Not Reported
		Norepinephrine			C					Not Reported
		Vasopressin			C					Not Reported
		Acetaminophen			C					Not Reported
		Albuterol [Salbutamol]			C					Not Reported
		Alprazolam			C					Not Reported
		Benzonatate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18014563	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482006		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Diamox [Acetazolamide]			C				Not Reported
	Insulin Human			C				Not Reported
	Cefepime			C				Not Reported
	Rocephine			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Metoprolol			C				Not Reported
	Furosemide			C				Not Reported
	Acetazolamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18078490	DIRECT	Y	OT			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18078499	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Cardiac Arrest; Liver Function Test Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18081104	EXPEDITED (15-DAY)		DE	IE-PFIZER INC-2020280589		43 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use; Product Use In Unapproved Indication	Vancomycin Hcl			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Meropenem			S		1 G, 3x/Day		Pfizer
	Piperacillin & Tazobactam			S		4.5 G, 4x/Day		Not Reported
	Co-Amoxiclave			S	Intravenous (not otherwise specified)	1.2 G, 3x/Day		Not Reported
	Clarithromycin			S		500 Mg, 2x/Day		Not Reported
	Remdesivir			S		Unk		Not Reported
	Salbutamol			C		Unk (Inhaler)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18084673	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486571		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Subcutaneous Emphysema	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once (Bolus Dose)		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd (Maintenance Dose)		Gilead

Acetaminophen	C	Unk	Not Reported
Albuterol [Salbutamol]	C	Unk	Not Reported
Ascorbic Acid	C	Unk	Not Reported
Atorvastatin	C	Unk	Not Reported
Azithromycin	C	Unk	Not Reported
Cefazolin	C	Unk	Not Reported
Cefepime	C	Unk	Not Reported
Chlorhexidine	C	Unk	Not Reported
Cholecalciferol	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Donepezil	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Guaifenesin	C	Unk	Not Reported
Hydrocodone/Acetaminophen	C	Unk	Not Reported
Insulin Aspart	C	Unk	Not Reported
Insulin, Regular	C	Unk	Not Reported
Losartan	C	Unk	Not Reported
Meclizine [Meclozine]	C	Unk	Not Reported
Melatonin	C	Unk	Not Reported
Methylprednisolone Sodium Succinate	C	Unk	Not Reported
Mupirocin	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Ondansetron	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Senna-S [Docusate Sodium; Sennoside A+B]	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported

	Zinc Sulfate			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085150	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Hepatic Failure; Renal Failure; Staphylococcal Infection; Staphylococcal Infection	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085180	DIRECT	Y	DE			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085188	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hepatic Function Abnormal; Renal Impairment	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085199	DIRECT	Y	DE			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Palliative Care	Remdesivir				S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085208	DIRECT	Y	DE			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Respiratory Distress	Remdesivir			S				Not Reported
	Docusate 100 Mg Po Bid			C				Not Reported
	Lovenox 70 Mg Iv Bid			C				Not Reported
	Insulin Sliding Scale			C				Not Reported
	Insulin Aspart 7 Units Sub Q Tid Wiht Meals			C				Not Reported
	Lantus Subq 17 Units Nightly			C				Not Reported
	Ativan 1 Mg Iv X1			C				Not Reported
	Losartan 25 Mg Po Daily			C				Not Reported
	Morphine 1 Mg Iv X1			C				Not Reported
	Morphine 4 Mg Iv X1			C				Not Reported
	Protonix 20 Mg Iv Daily			C				Not Reported
	Senna 1 Tablet Nightly			C				Not Reported
	Thiamine 100 Mg Iv Daily			C				Not Reported
	Precedex Titrated			C				Not Reported
	Morphine Pca			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085231	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Ondansetron			C				Not Reported
	Vancomycin			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085362	DIRECT	Y	DE			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Cardiac Arrest; Haemodialysis; Hypotension; Mental Status Changes; Renal Failure; Respiratory Failure; Tachycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085373	DIRECT	Y	HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085406	DIRECT	Y	HO, OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085562	DIRECT	Y	HO			69 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085591	DIRECT	Y	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir	S	Intravenous bolus			Gilead
	Albuterol Inhalation	C				Not Reported
	Aspirin	C				Not Reported
	Atorvastatin	C				Not Reported
	Budesonide Neb	C				Not Reported
	Fluticasone Nasal	C				Not Reported
	Furosemide	C				Not Reported
	Guaifenesin	C				Not Reported
	Hydralazine Inj	C				Not Reported
	Lorazepam	C				Not Reported
	Losartan	C				Not Reported
	Melatonin	C				Not Reported
	Zinc Sulfate	C				Not Reported
	Ivermectin	C				Not Reported
	Thiamin	C				Not Reported
	Vancomycin	C				Not Reported
	Amlodipine	C				Not Reported
	Ascorbic Acid Iv	C				Not Reported
	Azithromycin	C				Not Reported
	Cefepime	C				Not Reported
	Famotidine	C				Not Reported
	Heparin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085602	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Liver Disorder; Shock; Staphylococcal Sepsis	Remdesivir	Y		S	Intravenous bolus			Gilead
	Cisatracurium			C				Not Reported
	Norepinephrine			C				Not Reported
	Nafcillin			C				Not Reported
	Midazolam Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085661	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous bolus			Gilead
	Gabapentin 300mg Tid			C				Not Reported
	Insulin Glargine 35 Units Bid			C				Not Reported
	Pantoprozole 40mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085672	DIRECT	Y	DE, OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Amiodarone Ivpb			C				Not Reported
	Azithromycin 500mg Q24h			C				Not Reported
	Enoxaparin 73mg Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085683	DIRECT	Y	HO			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium	Remdesivir	Y		S				Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085716	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Ecchymosis; Infusion Site Bruising; Infusion Site Extravasation; Infusion	Remdesivir	Y		S	Intravenous drip			Gilead
	Ceftriaxone			C				Not Reported

Site Pain; Localised Oedema

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085726	DIRECT	Y	OT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085736	DIRECT	Y	DE			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Bacteraemia; Device Related Thrombosis; General Physical Health Deterioration; Haemofiltration; Hypotension; Klebsiella Bacteraemia; Pulmonary Embolism; Shock; Therapy Interrupted; Transaminases Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Epoprostenol Nebulization			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Cisatracurium Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085747	DIRECT	Y				60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Transaminases Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085776	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Cardio-Respiratory Arrest; General Physical Health Deterioration; Hypotension; Unresponsive To Stimuli	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ascobic Acid			C				Not Reported
	Cholesclciferol			C				Not Reported
	Dexamehasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Humulin 70/30			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Pantoprazole			C				Not Reported
	Zinc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085784	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486567		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Death; Myasthenia Gravis Crisis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once (Bolus Dose)		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd (Maintenance Dose)		Gilead
	Acetaminophen			C		Unk		Not Reported
	Alprazolam			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Dexmedetomidine			C				Not Reported
	Diphenhydramine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Hydrocortisone Sodium			C		Unk		Not Reported

	Succinate				
	Mupirocin	C	Unk		Not Reported
	Mycophenolate	C	Unk		Not Reported
	Norepinephrine	C	Unk		Not Reported
	Vitamin D [Colecalciferol]	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085785	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Irritation; Eye Pain; Infusion Related Reaction; Infusion Site Erythema; Infusion Site Swelling; Lacrimation Increased; Rash Erythematous; Therapy Interrupted; Vision Blurred	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085795	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085849	DIRECT	Y	HO			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085859	DIRECT	Y	HO			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085876	DIRECT	Y	DE			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Bilirubin Increased; Blood Calcium Decreased; Blood Creatinine Increased; Blood Glucose Increased; Blood Lactate Dehydrogenase Increased; Blood Magnesium Increased; Blood Phosphorus Increased; Blood Potassium Increased; Blood Sodium Decreased; C-Reactive Protein Increased; Haemoglobin Decreased; Hyperphosphatasaemia; Pneumonia Pseudomonal; Procalcitonin Increased; Protein Total Decreased; Red Blood Cell Count Decreased; Red Blood	Remdesivir	Y		S	Intravenous drip			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Amiodarone Iv Drip			C				Not Reported
	Amlodopine 5 Mg Po Bid			C				Not Reported
	Aspirin 81 Mg Ec Po Once Daily			C				Not Reported
	Atorvastatin 40 Mg Po Daily At Hs			C				Not Reported
	Cefepime 2 Gm Iv			C				Not Reported
	Ceftoloazane/Tazobactam 0.75 Gm Iv			C				Not Reported
	Clopidogrel 75 Mg Po Once Daily			C				Not Reported
	Enoxaparin 60 Mg Sq Q 12hr			C				Not Reported
	Ezetimibe 10 Mg Po Daily			C				Not Reported
	Famotidine 20 Mg Po Daily			C				Not Reported
	Meropenem Iv Renally Adjusted			C				Not Reported
	Metoprolol 25 Mg Po Q8hr			C				Not Reported
	Pravastatin 20 Mg Po Once Daily			C				Not Reported

Cell Sedimentation Rate Increased; Refusal Of Treatment By Relative; Renal Impairment; Somnolence; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085898	DIRECT	Y	HO			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Atracurium			C				Not Reported
	Chlorhexidine			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085938	DIRECT	Y	OT			89 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ampicillin/Sulbactam			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Heparin 5000u			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18085947	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Haemodialysis; Hypotension; Hypoxia; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Ascorbic Acid 1000 Mg Po Q12h			C				Not Reported
	Aspirin 81 Mg Po Daily			C				Not Reported
	Atorvastatin 80 Mg Po Hs			C				Not Reported
	Azithromycin 500 Iv X 1, Then 250 Mg Po Once Daily			C				Not Reported
	Cefepime 1 Gm Iv Q6hr			C				Not Reported
	Cholecalciferol 2, 0000 Units Po Daily			C				Not Reported
	Clopidogrel 75 Mg Po Once Daily			C				Not Reported
	Cyanocobalamin 1,000 Mcg Po Once Daily			C				Not Reported
	Enoxaparin 40 Mg Sq Q12hr			C				Not Reported
	Enoxaparin 100 Mg Sq Q12hr			C				Not Reported
	Famotidine 10 Mg Po Once Daily			C				Not Reported
	Famotidine 20 Mg Po Once Daily			C				Not Reported
	Meropenem 500 Mg Iv Renally Dosed			C				Not Reported
	Thiamine 100 Mg Po Once Daily			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2020	18086678	DIRECT	Y	HO, RI			6 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Qt Prolonged	Remdesivir Iv 0.4 Mg/Ml	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexmedetomidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	17942222	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474770		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Decreased; Condition Aggravated; Death; Disseminated Intravascular Coagulation; Hypothermia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin			C		Unk		Not Reported
	Aspirin (E.C.) [Aspirin]			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Duoneb			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Valacyclovir Hcl			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18055651	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484380		97 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Death	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead
	Carboxymethylcellulose Sodium			C		Unk		Not Reported
	Ceftaroline			C		Unk		Not Reported
	Premarin			C	Vaginal	Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18082333	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486234		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; General Physical Health Deterioration	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18082535	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486581		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once (Bolus Dose)		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd (Maintenance Dose)		Gilead
	Bupropion			C		Unk		Not Reported
	Chlorhexidine			C		Unk		Not Reported
	Citalopram			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Diphenhydramine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin, Regular			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Mupirocin			C		Unk		Not Reported
	Nifedipine			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Tamsulosin			C		Unk		Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18085960	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Pressure Decreased; Disseminated Intravascular Coagulation; Therapy Non-Responder	Remdesivir	Y		S	Intravenous drip	Other Frequency:200mg X 1,100mg Qd;		Gilead
	Atracurium			C				Not Reported
	Atropine			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Hydrocortisone Sod Succ			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Nph			C				Not Reported
	Melatonin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Vancomycin			C				Not Reported
	Dopamine			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Regular			C				Not Reported
	Isoproterenol			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18085980	DIRECT	Y	OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia	Remdesivir			S			5 DAY	Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087217	DIRECT					79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyperkalaemia	Remdesivir			S			5 DAY		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087222	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087224	DIRECT		OT			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087255	DIRECT	Y	OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Renal Impairment	Remdesivir			S				Not Reported
	Furosemide			C				Not Reported
	Norepinephrine			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087258	DIRECT	Y	OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Vomiting	Remdesivir			S	Intravenous bolus		5 DAY	Gilead
	Ascorbic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Detemir			C				Not Reported

	Zinc Sulfate	C		Not Reported
	Codeine-Guaifenesin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087261	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Colitis; Hypotension; Pneumonia; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087267	DIRECT	Y	DE			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Hydroxychloroquine			S	Oral		5 DAY	Not Reported
	Ns Fluid			C				Not Reported
	Albumin 25%			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Potassium Chloride Ivpb			C				Not Reported
	Propofol			C				Not Reported
	Remdesivir			S				Not Reported
	Sodium Bicarbonate Large Volume			C				Not Reported
	Acetaminophen 500mg Tablet			C				Not Reported
	Ascorbic Acid Tablet			C				Not Reported
	Cholecalciferol 5000 Unit Tablet			C				Not Reported
	Dexamethasone 6mg Po Daily			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin 40mg Sq Q24h			C				Not Reported
	Enoxaparin 60mg Sq Q12h			C				Not Reported
	Etomidate Iv			C				Not Reported
	Furosemide 20mg Ivp			C				Not Reported
	Furosemide 40mg Ivp			C				Not Reported
	Insulin Aspart			C				Not Reported
	Ivermectin 12 Po X 1			C				Not Reported
	Ondansetron Ivp			C				Not Reported

	Remdesivir	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087333	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486207		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Rocephin [Ceftriaxone Sodium]			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Sodium Phosphate			C		Unk		Not Reported
	Fentanyl Citrate			C		Unk		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Norepinephrine Bitartrate			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18087532	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0486136		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atracurium			C				Not Reported
	Insulin Glargine			C				Not Reported
	Chlorhexidine Gluconate			C				Not Reported
	Sennosides			C				Not Reported
	Docusate			C				Not Reported

		Albuterol Hfa			C					Not Reported
		Rocuronium B Brau			C					Not Reported
		Dexamethasone Sodium Phosphate			C					Not Reported
		Piperacillin			C					Not Reported
		Fentanyl			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088069	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486162		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Dysphagia; General Physical Health Deterioration	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)	5 Mg, Qd		Not Reported
	Carvedilol			C	Oral	3.125 Mg, Bid		Not Reported
	Valproate Sodium			C		500 Mg		Not Reported
	Ticagrelor			C	Oral	90 Mg Q12h		Not Reported
	Spironolactone			C	Oral	25 Mg, Qd		Not Reported
	Entresto			C	Oral	24/26		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Megestrol			C	Oral	400 Mg, Bid		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported
	Fluconazole			C	Oral	100 Mg, Qd		Not Reported
	Ezetimibe			C	Oral	10 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	80 Mg Q12hr		Not Reported
	Atorvastatin			C	Oral	80 Mg		Not Reported
	Asa			C	Oral	81 Mg, Once		Not Reported
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	Unk, Bid		Not Reported

	Clinimix E			C		Unk				Not Reported
	Tpn [Amino Acids Nos; Carbohydrates Nos;Minerals Nos;Vitamins Nos]			C		Unk				Not Reported
	Thiamine			C	Oral	Unk Unk, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18088776	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486244		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089307	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486950		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Covid-19; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Amiodarone			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18089399	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486606		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Metoprolol [Metoprolol Fumarate]			C				Not Reported

		Heparin			C					Not Reported
		Doxazosin			C					Not Reported
		Dexamethasone			C					Not Reported
		Clopidogrel			C					Not Reported
		Aspirin 81			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090945	DIRECT	Y				27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Tachycardia; Vomiting	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Not Reported
	Normal Saline Infusion			C				Not Reported
	Acetaminophen 1000mg Tab			C				Not Reported
	Acetaminophen 650mg Tab			C				Not Reported
	Aspirin 81mg Chewable Tab			C				Not Reported
	Azithromycin 500mg Tab			C				Not Reported
	Ceftriaxone 1g In 100ml Ns			C				Not Reported
	Enoxaparin 40mg Syringe			C				Not Reported
	Risaquad Capsule			C				Not Reported
	Methylprednisolone 40mg Iv			C				Not Reported
	Montelukast 10mg Tab			C				Not Reported
	Zofran 4mg Inj			C				Not Reported
	Potassium Chloride Cr 40meq			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090946	DIRECT	Y	DE			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S		Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090948	DIRECT	Y	DE			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest	Remdesivir	S	Intravenous drip	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090949	DIRECT	Y	HO			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Nephropathy Toxic	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090950	DIRECT	Y	HO, OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Condition Aggravated; Renal Injury; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Diphenhydramine			C				Not Reported
	Metronidazole			C				Not Reported
	Olanzapine			C				Not Reported
	Tocilizumab			C				Not Reported
	Vancomycin			C				Not Reported
	Sennoside			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090951	DIRECT	Y				22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Azithromycin 500mg In 250mg Ns			C				Not Reported
	Iodixanol 320mg/Ml 100ml			C				Not Reported
	Acetaminophen 650mg Tab			C				Not Reported

	Aspirin 81mg Tab	C							Not Reported
	Benzonatate Capsule 100mg	C							Not Reported
	Tums 500mg	C							Not Reported
	Ceftriaxone 2g In Ns 100ml	C							Not Reported
	Mucinex Dm 30/600mg	C							Not Reported
	Doxycycline 100mg In 100ml Ns	C							Not Reported
	Enoxaparin 40mg Syrnge	C							Not Reported
	Guaifenesin-Codeine 100-10mg/5ml	C							Not Reported
	Maraviroc 300mg	C							Not Reported
	Methylprednisolone 125mg	C							Not Reported
	Prednisone 40mg Tab	C							Not Reported
	Normal Saline 500ml	C							Not Reported
	Vitamin C 500mg	C							Not Reported
	Cholecalciferol 25mcg	C							Not Reported
	Zinc Sulfate Cap 220mg	C							Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090952	DIRECT	Y	LT			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090953	DIRECT	Y				80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 200 Mg			C				Not Reported
	Remdesivir 100 Mg			C				Not Reported
	Albuterol			C				Not Reported
	Apixaban			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Budesonide			C				Not Reported

		Cholecalciferol			C					Not Reported
		Dexamethasone			C					Not Reported
		Levofloxacin			C					Not Reported
		Levothyroxine			C					Not Reported
		Memantine			C					Not Reported
		Metoprolol			C					Not Reported
		Pantoprazole			C					Not Reported
		Zinc			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090954	DIRECT	Y	HO, LT, OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous bolus			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			C				Not Reported
	Propofol			C				Not Reported
	Potassium Phosphate			C				Not Reported
	Miralax			C				Not Reported
	Norepinephrine			C				Not Reported
	Morphine			C				Not Reported
	Butmetanide			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090955	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090956	DIRECT	Y	OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18090957	DIRECT	Y	DE			91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2020	18093125	DIRECT	Y	DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Therapy Interrupted; Vascular Access Complication	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17970934	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477763		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Heparin Axicur			C				Not Reported

	Insulin			C				Not Reported
	Cefepime			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Docusate			C				Not Reported
	Epinephrine			C				Not Reported
	Hydromorphone			C				Not Reported
	Methylprednisolone			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Sennoside [Sennoside A+B]			C				Not Reported
	Sucralfate			C				Not Reported
	Vancomycin			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	17979287	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478145		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Product Preparation Error	Remdesivir			S	Intravenous drip	200 Mg/M2, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18021692	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482369		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Lisinopril			C				Not Reported
	Gabapentin			C				Not Reported
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxepin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18091971	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported
	Apixaban			C				Not Reported
	Guaifenesin			C				Not Reported
	Levothyroxine			C				Not Reported
	Metoprolol Succinate Xl			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092382	DIRECT	Y				38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092386	DIRECT	Y	HO			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Apixaban			C				Not Reported
	Cistatracurium			C				Not Reported
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Midazolam			C				Not Reported

	Norepinephrine			C						Not Reported
	Propofol			C						Not Reported
	Vasopressin			C						Not Reported
	Nortriptyline			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18092389	DIRECT	Y	DE			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Diltiazem			C				Not Reported
	Furosemide			C				Not Reported
	Metoprolol			C				Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C				Not Reported
	Ketorolac			C				Not Reported
	Lorazepma			C				Not Reported
	Morphine			C				Not Reported
	Enoxaparin			C				Not Reported
	Docusate			C				Not Reported
	Famotidine			C				Not Reported
	Omeprazole			C				Not Reported
	Senna			C				Not Reported
	Dexamethasone			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18093860	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486676		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Respiratory Distress	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Docusate			C	Oral	100 Mg, Bid		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Intravenous (not otherwise specified)	70 Mg, Bid		Not Reported
	Insulin			C		Sliding Scale		Not Reported

	Insulin Aspart		C	Subcutaneous	7 Iu, Tid With Meals	Not Reported
	Lantus		C	Subcutaneous	17 Iu, Qhs	Not Reported
	Ativan		C	Intravenous (not otherwise specified)	1 Mg	Not Reported
	Losartan		C	Oral	25 Mg, Qd	Not Reported
	Morphine		C	Intravenous (not otherwise specified)	1 Mg	Not Reported
	Morphine		C	Intravenous (not otherwise specified)	4 Mg	Not Reported
	Morphine		C	Intravenous (not otherwise specified)	Pca	Not Reported
	Protonix		C	Intravenous (not otherwise specified)	20 Mg, Qd	Not Reported
	Senna Acutifolia		C	Oral	1 Tablet, Qhs	Not Reported
	Thiamine		C	Intravenous (not otherwise specified)	100 Mg, Qd	Not Reported
	Precedex		C		Titrated	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18095728	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486976		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C				Not Reported
	Dexamethasone			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Cholecalciferol			C				Not Reported
	Clopidogrel			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Enoxaparin			C				Not Reported

		Famotidine			C						Not Reported
		Meropenem			C						Not Reported
		Thiamine			C						Not Reported
		Zinc			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096015	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487389		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096598	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486979		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Hypoxia; Pneumonia Pseudomonal; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Plasma			C				Not Reported
	Dexamethasone			C				Not Reported
	Amiodarone			C				Not Reported
	Amlodipine			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Cefepime			C				Not Reported
	Ceftolozane			C				Not Reported
	Tazobactam			C				Not Reported
	Clopidogrel			C				Not Reported
	Enoxaparin			C				Not Reported
	Ezetimibe			C				Not Reported
	Famotidine			C				Not Reported
	Meropenem			C				Not Reported
	Metoprolol			C				Not Reported
	Pravastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096871	DIRECT	Y	DE, DS, HO, LT, OT			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Herniation; Brain Injury; Brain Oedema; Cardiac Arrest	Remdesivir			S	Intravenous bolus			Not Reported
	Remdesivir			S	Intravenous bolus			Not Reported
	Convalescent Plasma			C				Not Reported
	Tocilizumab			C				Not Reported
	Decadron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096880	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypoxia; Respiratory Acidosis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Ascorbic Acid 1000 Mg Po Once Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Azithromycin 500 Mg Iv Once Daily			C				Not Reported
	Enoxaparin 70 Mg Sq Q12hrs			C				Not Reported
	Famotidine 20 Mg Iv Q12hr			C				Not Reported
	Insulin Glargine 10 Units Sq At Hs			C				Not Reported
	Insulin Glargine 15 Units Sq Bid			C				Not Reported
	Smz/Tmp Iv Q6hr			C				Not Reported
	Zinc Sulfate 220 Mg Po Once Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096891	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096906	DIRECT	Y	DE			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Complication	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096915	DIRECT	Y	DE			96 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Flagyl			C				Not Reported
	Albuterol			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096967	DIRECT	Y				81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Flushing; Oxygen Saturation Decreased	Veklury (Remdesivir)	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Albuterol/Ipratropium			C				Not Reported
	Restasis			C				Not Reported
	Ibuprofen			C				Not Reported
	Pantoprazole			C				Not Reported
	Aspirin			C				Not Reported
	Fluticasone Propionate			C				Not Reported

	Miralax			C					Not Reported
	Simvastatin			C					Not Reported
	Dexamethasone			C					Not Reported
	Enoxaparin			C					Not Reported
	Labetalol			C					Not Reported
	Hydralazine			C					Not Reported
	Benzonatate			C					Not Reported
	Guaifenesin			C					Not Reported
	Acetaminophen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18096997	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097007	DIRECT	Y	HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Creatinine Renal Clearance Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097016	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duplicate Therapy Error; Product Dispensing Error; Product Prescribing Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Azithromycin			C				Not Reported
	Ascorbic Acid			C				Not Reported

	Enoxaparin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097027	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Esmolol			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Furosemide			C				Not Reported
	Meropenem			C				Not Reported
	Micafungin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097038	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Rosuvastatin			C				Not Reported
	Rocuronium			C				Not Reported
	Norepinephrine			C				Not Reported
	Fentanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097047	DIRECT	Y	OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not			Gilead

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097065	DIRECT	Y	OT			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenasin			C				Not Reported
	Hydrocodone-Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097076	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip		10 DAY	Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Pantoprazole			C				Not Reported
	Levothyroxine			C				Not Reported
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Tociluzimab			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Ipratropium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097088	DIRECT	Y	OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dystonia	Remdesivir			S						Not Reported
	Compazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097098	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097531	DIRECT	Y	HO, RI, OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Interrupted	Remdesivir 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097822	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486167		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amiodarone			C	Oral	200 Mg		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	100 Mg		Not Reported
	Famotidine			C	Intravenous (not	20 Mg, Bid		Not Reported

						otherwise specified)				
	Lantus			C		Subcutaneous	Up To 20 Iu			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18097839	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486577		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Death; Drug Ineffective; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Q24h		Gilead
	Acetaminophen			C	Oral	1000 Mg, Q6h Prn		Not Reported
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	2 Puffs, Q8h		Not Reported
	Alprazolam			C		0.25 Mg, Q6h Prn		Not Reported
	Amlodipine			C	Oral	5-10 Mg		Not Reported
	Ascorbic Acid			C	Oral	1000 Mg, Tid		Not Reported
	Atorvastatin			C	Oral	40 Mg, Qhs		Not Reported
	Chlorhexidine			C	Oral	15 Ml, Bid		Not Reported
	Cholecalciferol			C	Oral	20000 Units		Not Reported
	Clonidine			C	Oral	0.1-0.2 Mg		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg Q12-24hr		Not Reported
	Diphenhydramine			C	Intravenous (not otherwise specified)	25 Mg Q6h Prn		Not Reported
	Enoxaparin			C	Subcutaneous	30-90 Mg Q24h		Not Reported
	Famotidine			C	Oral	20 Mg, Qd		Not Reported
	Gabapentin			C	Oral	100 Mg, Tid		Not Reported
	Hydralazine			C	Intravenous (not otherwise specified)	10 Mg Q 6 Hr Prn		Not Reported
	Levofloxacin			C	Intravenous (not	500 Mg Q 28 Hr		Not Reported

			otherwise specified)		
	Lorazepam	C	Intravenous (not otherwise specified)	0.5 Mg Q4hr Prn	Not Reported
	Mupirocin	C	Nasal	Unk, Bid	Not Reported
	Ondansetron	C	Intravenous (not otherwise specified)	4 Mg Q 8 Hr Prn	Not Reported
	Patiromer Sorbitex Calcium	C	Ophthalmic	8.4 G, Once	Not Reported
	Sodium Bicarbonate	C	Oral	650-1300 Bid-Tid	Not Reported
	Sodium Bicarbonate In Dextrose 5%	C	Intravenous (not otherwise specified)	Continuous	Not Reported
	Sodium Bicarbonate In Dextrose 5%	C	Intravenous (not otherwise specified)	Unk Continuous	Not Reported
	Sodium Polystyrene Sulfonate	C	Oral	15 G, Qd	Not Reported
	Sucralfate	C	Oral	1 G, Q6h	Not Reported
	Timolol Maleate 0.5%	C		1 Drop Both Eyes, Bid	Not Reported
	Zinc Sulfate	C	Oral	220 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2020	18098576	DIRECT	Y	RI, OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased; Therapy Cessation	Remdesivir 100mg Injection	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg Injection	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17818827	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0468514		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death; Respiratory Distress	Remdesivir	S	Unknown	100 Mg	Gilead
	Cyclobenzaprine	C		Unk	Not Reported
	Aspirin Ec	C		Unk	Not Reported
	Doxycycline	C		Unk	Not Reported
	Pyridostigmine	C		Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Calcium Carbonate	C		Unk	Not Reported
	Zinc	C		Unk	Not Reported
	Ondansetron	C		Unk	Not Reported
	Diphenhydramine	C		Unk	Not Reported
	Amiodarone	C		Unk	Not Reported
	Famotidine	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Albuterol [Salbutamol]	C		Unk	Not Reported
	Furosemide	C			Not Reported
	Insulin Detemir	C			Not Reported
	Lorazepam	C			Not Reported
	Metoprolol	C			Not Reported
	Potassium Chloride	C			Not Reported
	Apixaban	C			Not Reported
	Cefepime	C			Not Reported
	Chlorhexidine	C			Not Reported
	Dexmedetomidine	C			Not Reported
	Fentanyl	C			Not Reported
	Heparin	C			Not Reported
	Insulin Aspart	C			Not Reported
	Ketamine	C			Not Reported
	Metronidazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17881226	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470048		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Melatonin	C				Not Reported
	Levothyroxine	C				Not Reported
	Propofol	C				Not Reported
	Norepinephrine	C				Not Reported
	Insulin	C				Not Reported
	Insulin Lispro	C				Not Reported
	Hydromorphone	C				Not Reported
	Meropenem	C				Not Reported
	Prismasol	C				Not Reported
	Linezolid	C				Not Reported
	Famotidine	C				Not Reported
	Heparin	C				Not Reported
	Lisinopril	C				Not Reported
	Diclofenac	C				Not Reported
	Insulin Aspart	C				Not Reported
	Insulin Glargine	C				Not Reported
	Convalescent Plasma	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	17952475	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0475664		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Heart Rate Increased; Maternal Exposure During Pregnancy	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18013909	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0481352			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not	200 Mg		Gilead

					otherwise specified)				
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg			Gilead
	Propofol			S	Unknown				Not Reported
	Fentanyl			C					Not Reported
	Midazolam			C					Not Reported
	Atropine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18021543	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482491		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200/100mg, Qd		Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Pantoprazole			C	Oral	40 Mg		Not Reported
	Valsartan			C	Oral	320 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18038072	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470345		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Haemoglobin Decreased; Hypernatraemia; Melaena; Mental Status Changes; Ulcer Haemorrhage	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral			Not Reported
	Amlodipine			C	Oral			Not Reported
	Diclofenac			C	Oral			Not Reported

		Finasteride			C	Oral				Not Reported
		Lisinopril			C	Oral				Not Reported
		Pantoprazole			C	Intravenous (not otherwise specified)				Not Reported
		Simvastatin			C	Oral				Not Reported
		Tamsulosin			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18097139	DIRECT	Y				67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Mstt1041a			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099278	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487565		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C				Not Reported
	Dexamethasone			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Smz-Tmp			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Bicarbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099507	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487050		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Azithromycin			C		250 Mg		Not Reported
	Famotidine			C		20 Mg, Bid		Not Reported
	Ceftriaxone			C		1 G Q24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099542	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487536		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18099549	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487413		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Fentyl			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Rocuronium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18100350	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487983		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	200 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18100399	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487417		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Apixaban			C		5 Mg, Bid		Not Reported
	Bupropion			C		50 Mg, Tid		Not Reported
	Duloxetine			C		30 Mg, Qd		Not Reported
	Aripiprazole +Pharma			C		5 Mg, Bid		Not Reported
	Insulin Glargine			C		15 Units Hs		Not Reported
	Levothyroxine			C		100 Mcg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18100913	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487393		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead
	Hydroxychloroquine			S	Oral	400 Mg, Bid		Not Reported
	Albumin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Potassium Chloride			C				Not Reported
	Propofol			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported

		Enoxaparin			C							Not Reported
		Etomidate			C							Not Reported
		Furosemide			C							Not Reported
		Insulin			C							Not Reported
		Ivermectin			C							Not Reported
		Ondansetron			C							Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18102972	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;		Gilead
	Tocilizumab			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18102974	DIRECT	Y	OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Remdesivir			S				Not Reported
	Ceflriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103011	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Bumetanide			C				Not Reported
	Heparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Tocilizumab			C				Not Reported
	Insulin Nph			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported

	Fentanyl			C					Not Reported
	Propofol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103017	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albumin			C				Not Reported
	Cisatracurium			C				Not Reported
	Epoprostenol			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Nph			C				Not Reported
	Lactobacillus			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Phenylephrine			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Propofol			C				Not Reported
	Sodium Polystyrene Sulfonate			C				Not Reported
	Tocilizumab			C				Not Reported
	Vaopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103026	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip	Other Frequency:X1, Then 100 Mg Qd;		Gilead
	Solu-Medrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103031	DIRECT	Y	OT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Atracurium			C				Not Reported
	Epinephrine			C				Not Reported
	Cefepime			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Hydrocodone			C				Not Reported
	Hydrocortisone			C				Not Reported
	Labetalol			C				Not Reported
	Humulin R			C				Not Reported
	Duoneb			C				Not Reported
	Midazolam			C				Not Reported
	Levophed			C				Not Reported
	Ondansetron			C				Not Reported
	Promethazine			C				Not Reported
	Vasopressin			C				Not Reported
	Rocuronium			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103049	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous drip			Gilead
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxparin			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Glargine			C				Not Reported

		Insulin Lispro			C					Not Reported
		Ipratropium			C					Not Reported
		Metoprolol			C					Not Reported
		Multivitamin			C					Not Reported
		Ondansetron			C					Not Reported
		Piperacillin/Tazobactam			C					Not Reported
		Zinc Sulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103051	DIRECT	Y	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Hypothermia; Oxygen Saturation Decreased	Remdesivir			S				Not Reported
	Insulin Isophane/Reg 70/30			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103066	DIRECT	Y	OT			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Critical Illness; Liver Function Test Increased; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Codeine-Guifenesin			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Linezolid			C				Not Reported
	Midazolam			C				Not Reported
	Multivitamin With Iron			C				Not Reported
	Norepinephrine			C				Not Reported
	Perfluten Lipid Microspheres			C				Not Reported
	Polyethylene Glycol (Glycolax)			C				Not Reported

		Potassium Chloride			C					Not Reported
		Propofol			C					Not Reported
		Rocuronium			C					Not Reported
		Sennosides			C					Not Reported
		Vancomycin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103069	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Glomerular Filtration Rate Decreased; Hypotension; Urine Output Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Doxycyline			C				Not Reported
	Hydrocortisone			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Quetiapine			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103071	DIRECT	Y	DE			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported
	Doxazosin			C				Not Reported
	Furosemide			C				Not Reported
	Isosorbide Dinitrate			C				Not Reported
	Losartan			C				Not Reported
	Metoprolol			C				Not Reported
	Aspirin			C				Not Reported
	Gabapentin			C				Not Reported
	Morphine			C				Not Reported
	Oxycodone-Acetaminophen			C				Not Reported
	Ropinirole			C				Not Reported
	Vecuronium			C				Not Reported
	Enoxaparin			C				Not Reported
	Ticagrelor			C				Not Reported

		Famotidine			C					Not Reported
		Atorvastatin			C					Not Reported
		Insulin			C					Not Reported
		Amitriptyline			C					Not Reported
		Duloxetine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103075	DIRECT	N	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Temazepam			C				Not Reported
	Senna			C				Not Reported
	Ondansetron			C				Not Reported
	Nystatin			C				Not Reported
	Dexamethosone			C				Not Reported
	Enoxaparin			C				Not Reported
	Robitussin			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103076	DIRECT	N	OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dilaudid			C				Not Reported
	Tylenol			C				Not Reported
	Norvasc			C				Not Reported
	Albuterol			C				Not Reported
	Zofran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103088	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip		5 DAY	Not Reported
	Acetaminophen			C				Not Reported
	Atorvastatin			C				Not Reported
	Citalopram			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103093	DIRECT	Y				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucination, Auditory	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103095	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Dose Omission Issue	Remdesivir			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103097	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration	Remdesivir	Y		S	Intravenous (not		5 DAY	Gilead

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103366	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)			Gilead
	Albuterol Inhaler			C				Not Reported
	Ascorbic Acid Iv			C				Not Reported
	Aspirin Enteric Coated			C				Not Reported
	Benzonatate			C				Not Reported
	Budesonide Respule			C				Not Reported
	Doxycycline Iv			C				Not Reported
	Enoxaparin			C				Not Reported
	Enoxaparin			C				Not Reported
	Heparin Subq			C				Not Reported
	Insulin Regular			C				Not Reported
	Insulin Glargine			C				Not Reported
	Levothyroxine			C				Not Reported
	Proprofol			C				Not Reported
	Rocuronium			C				Not Reported
	Ropinirole			C				Not Reported
	Rosuvastatin			C				Not Reported
	Albuterol/Ipratropium			C				Not Reported
	Cefepime			C				Not Reported
	Dexmethasone			C				Not Reported
	Fentanyl Pca			C				Not Reported
	Pantoprazole Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18103897	DIRECT	N	DE			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Blood Creatinine Increased; Blood Urea Increased;	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified) Intravenous (not	Frequency: Once		Gilead

Cardiac Arrest; Disease Progression; Hypercapnia; Oxygen Saturation Decreased; Pulseless Electrical Activity; Pyrexia; Respiratory Failure; Urine Output Decreased	otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2020	18104113	DIRECT	Y	DE			16 YR	Female	UMI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Blood Creatinine Increased; Blood Urea Increased; Cardiac Arrest; Condition Aggravated; Disease Progression; Drug Ineffective; Hypercapnia; Oxygen Saturation Decreased; Pulseless Electrical Activity; Pyrexia; Renal Impairment; Respiratory Failure; Urine Output Decreased	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Not Reported
	Gilead Sclences			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18101474	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-255176		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Death; Drug Ineffective; Heparin-Induced Thrombocytopenia; Hypotension; Platelet Count Decreased;	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Bivalirudin			S	Unknown	0.15 Mg/Kg/H		Not Reported

Pulmonary Embolism; Tachycardia	Unfractionated Heparin	S	Unknown	5000 Unit, Bid		Not Reported
	Unfractionated Heparin	S		18 Units/Kg/H		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Cisatracurium	S	Unknown	Unk		Not Reported
	Remdesivir	S	Unknown	Unk		Not Reported
	Vasopressin	S	Unknown	Unk		Not Reported
	Norepinephrine	S	Unknown	Unk		Not Reported
	Nitric Oxide	S		Unk		Not Reported
	Tenecteplase	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103103	DIRECT		DE			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103107	DIRECT		DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103111	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103116	DIRECT	Y	OT			25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetylcysteine			C				Not Reported
	Ascorbic Acid Iv			C				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported
	Dexamethasone 6 Mg Iv			C				Not Reported
	Zinc Sulfate 200 Mg Po Bid			C				Not Reported
	Enoxaparin 1 Mg/Kg Subq Bid			C				Not Reported
	Docusate 100 Mg Po Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103144	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Disease Complication	Remdesivir			S	Intravenous drip		5 DAY	Gilead
	Acetaminophen 650mg Tab			C				Not Reported
	Albuterol-Ipratropium 2.5-0.5 mg/3ml Nebulizer Soln			C				Not Reported
	Aspirin 81mg Chew Tab			C				Not Reported
	Azithromycin 500mg In Ns 250ml			C				Not Reported
	Dexamethasone 10mg In 50ml Ns			C				Not Reported
	Dexmedotomidine 500mcg In 100ml Ns			C				Not Reported
	Lovenox 100mg Syringe			C				Not Reported
	Lovenox 40mg Syringe			C				Not Reported
	Epoprostenol 1.5mg In 60ml Ns Inh Solution			C				Not Reported
	Famotidine 20mg Inj			C				Not Reported
	Furosemide 20mg Inj			C				Not Reported
	Ketamine 1000mg In 100ml Ns			C				Not Reported
	Oxycodone Ir 5mg Tab			C				Not Reported

		Lorazepam 2mg Tab		C					Not Reported
		Melatonin 3mg Tab		C					Not Reported
		Solu-Medrol 40mg		C					Not Reported
		Miconazole 2% With Zinc Oxide Cream		C					Not Reported
		Midazolam 2mg Inj		C					Not Reported
		Midodrine 10mg Tab		C					Not Reported
		Levophed In D5w		C					Not Reported
		Rocuronium 100mg		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103151	DIRECT	Y				56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen 160mg/5ml Soln			C				Not Reported
	Atropine 0.5mg Inj			C				Not Reported
	Azithromycin			C				Not Reported
	Bumetanide 10mg In 100ml D5!			C				Not Reported
	Ceftriaxone 1gram In 100ml Ns			C				Not Reported
	Clonazepam 2mg Tab			C				Not Reported
	Desmopressin 1mcg Inj			C				Not Reported
	Dopamine 400mg/250ml			C				Not Reported
	Enoxaparin 40mg Syr			C				Not Reported
	Enoxaparin 50mg Syr			C				Not Reported
	Veletri 1.5mg In 60ml Ns Inh Soln			C				Not Reported
	Famotidine 20mg Inj			C				Not Reported
	Furosemide 40mg Inj			C				Not Reported
	Unfractionated Heparin			C				Not Reported
	Hydromorphone Inj			C				Not Reported
	Ketamine 1000mg/100ml Ns			C				Not Reported
	Solumedrol			C				Not Reported
	Metolazone 10mg Tab			C				Not Reported
	Midodrine 20mg Tab			C				Not Reported
	Levophed 8mg/100ml			C				Not Reported
	Phenylephrine 100mg/250ml In Ns			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103159	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Acetaminophen 1000mg Tab			C				Not Reported
	Proventil Hfa			C				Not Reported
	Ceftriaxone 1g In 100ml Ns			C				Not Reported
	Azithromycin 500mg In Ns 250ml			C				Not Reported
	Lovenox 70mg Syr			C				Not Reported
	Furosemide 40mg Inj			C				Not Reported
	Gauifenesin-Dextromethorphan 100mg/10mg/5ml			C				Not Reported
	Lantus			C				Not Reported
	Humalog			C				Not Reported
	Humulin R			C				Not Reported
	Solumedrol			C				Not Reported
	Spiriva 18mcg Cap			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103165	DIRECT	Y	HO			31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Viral; Transaminases Increased	Remdesivir Iv			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin 40mg Sq			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103169	DIRECT		DE			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2020	18103174	DIRECT		DE			90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18103179	DIRECT	Y	OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Aspirin-Acetaminophen-Caffeine			C				Not Reported
	Prochlorperazine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Buproprion			C				Not Reported
	Ketorolac			C				Not Reported
	Lorazepam			C				Not Reported
	Nystatin Swish And Swallow			C				Not Reported
	Benzonatate			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18103184	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18103189	DIRECT	Y	DE			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Refusal Of Treatment By Patient	Remdesivir	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18103201	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Swelling	Remdesivir			S	Intravenous drip			Gilead
	Aspirin 81mg Chew Tab			C				Not Reported
	Benzonatate Cap 100mg			C				Not Reported
	Lovenox 40mg Syr			C				Not Reported
	Gabapentin 100mg Cap			C				Not Reported
	Lantus			C				Not Reported
	Humalog			C				Not Reported
	Ondansetron 4mg Inj			C				Not Reported
	Miralax			C				Not Reported
	Senna 8.6mg Tab			C				Not Reported
	Trazodone 50mg Tab			C				Not Reported
	Vitamin C 500mg Tab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18103206	DIRECT	Y				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Condition Aggravated; Dizziness; Hypoaesthesia; Therapy Interrupted	Remdesivir			S	Intravenous drip	Other Frequency:X1;		Gilead
	Acetaminophen 1000mg Tab			C				Not Reported
	Proventil Hfa			C				Not Reported
	Cetirizine 10mg Tab			C				Not Reported
	Enoxaparin 40mg Syr			C				Not Reported
	Enoxaparin 60mg Syr			C				Not Reported
	Famotidine 20mg Tab			C				Not Reported
	Furosemide Inj			C				Not Reported
	Lorazepam 0.25mg Tab			C				Not Reported
	Melatonin 3mg Tab			C				Not Reported
	Ondansetron 4mg Inj			C				Not Reported
	Klor-Con 50mg Cr Tab			C				Not Reported
	Saline Nasal Spray			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18103213	DIRECT	Y				73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18103220	DIRECT		DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2020	18103226	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Cessation	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17950546	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475646		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Unk		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	17951557	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0473011		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amiodarone			C		Unk		Not Reported
	Apixaban			C	Oral	5mg Q12h		Not Reported
	Diltiazem			C		Unk		Not Reported
	Metoprolol			C	Oral	12.5 Mg Q12h		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Tocilizumab			C		400 Mg, Once		Not Reported
	Heparin			C	Intravenous (not otherwise specified)	1150-1300 Units/Hr		Not Reported
	Adenosine			C	Intravenous (not otherwise specified)	6 Mg		Not Reported
	Tylenol			C				Not Reported
	Albuterol Hfa			C	Respiratory (inhalation)	180 Mcg Q6h		Not Reported
	Ipratropium			C	Respiratory (inhalation)	34 Mcg		Not Reported
	Ondansetron			C		4 Mg, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18021106	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482495		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cisatracurium			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported

					Insulin		C			Not Reported
					Ketamine		C			Not Reported
					Midazolam		C	Intravenous (not otherwise specified)	Unk	Not Reported
					Budesonide		C			Not Reported
					Carboxymethylcellulose		C	Ophthalmic	Unk	Not Reported
					Ipratropium Bromide And Albuterol Sulfate		C			Not Reported
					Norepinephrine		C			Not Reported
					Propofol		C	Intravenous (not otherwise specified)	Unk	Not Reported
					Gabapentin		C	Oral	Unk	Not Reported
					Aztreonam		C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18045042	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484008		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Plasma			C				Not Reported
	Oxygen			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported
	Epinephrine			C				Not Reported
	Phenylephrine			C				Not Reported
	Amiodarone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18052169	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482484		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death; Pyrexia	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cisatracurium	C		Unk		Not Reported
	Dexmedetomidine	C				Not Reported
	Enoxaparin	C	Subcutaneous	40 Mg		Not Reported
	Fentanyl	C		Unk		Not Reported
	Hydralazine	C		Unk		Not Reported
	Insulin	C		Unk		Not Reported
	Propofol	C	Intravenous (not otherwise specified)	Titrate		Not Reported
	Carboxymethylcellulose	C	Ophthalmic	Unk		Not Reported
	Norepinephrine	C		Unk		Not Reported
	Insulin Aspart	C	Subcutaneous	Sliding		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18103451	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0487735		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Arrest; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Diphenhydramine			C				Not Reported
	Metronidazole			C				Not Reported
	Olanzapine			C				Not Reported
	Vancomycin			C				Not Reported
	Sennoside A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18103742	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0487467		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Kidney Injury; Blood Creatinine Increased; Shock	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Unknown	Unk		Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Carvedilol			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Heparin			C	Unknown	Unk		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Vasopressin			C	Unknown	Unk		Not Reported
	Potassium Chloride			C	Unknown	Unk		Not Reported
	Epinephrine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18103755	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487454			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Preparation Issue	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104148	DIRECT	Y	DE			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104149	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104150	DIRECT	Y	LT			79 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Azithromycin 500 Mg Daily			C				Not Reported
	Lovenox 40 Mg Daily			C				Not Reported
	Gabpentin 300 Mg Tid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104151	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104152	DIRECT	Y	HO			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Chest Pain; Hepatomegaly; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Ascorbic Acid Iv			C				Not Reported
	Acetaminophen Prn			C				Not Reported
	Albuterol			C				Not Reported
	Belladonna/Opium Suppository			C				Not Reported
	Enoxaparin			C				Not Reported
	Montelukast			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Prednisone			C				Not Reported
	Dexamethasone			C				Not Reported
	Diltiazem			C				Not Reported
	Thiamine Iv			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104153	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone 6mg			C				Not Reported
	Pantoprazole 40mg			C				Not Reported
	Thiamine 100mg			C				Not Reported
	Vancomycin 1500mg			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Ketamine			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104154	DIRECT	Y				32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Ofirmev			C				Not Reported
	Pantoprazole			C				Not Reported
	Lantus			C				Not Reported
	Fish Oil			C				Not Reported
	Fenofibrate			C				Not Reported
	Humalog			C				Not Reported
	Primaxin			C				Not Reported
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Doxycycline			C				Not Reported
	Benzonatate			C				Not Reported
	Tramadol			C				Not Reported
	Dexamethasone Iv			C				Not Reported
	Iopamidol 76% Injection			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104155	DIRECT	Y	DE			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104156	DIRECT	Y	OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir Injection			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported

	Cefepime			C						Not Reported
	Vancomycin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104162	DIRECT	Y	HO			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Urea Abnormal; Glomerular Filtration Rate Abnormal	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104356	DIRECT	Y	HO			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104603	DIRECT	Y	OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Aspirin			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18104604	DIRECT	Y				70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Phenylephrine			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Albuerol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106508	DIRECT	Y	LT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Haemodialysis; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106544	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106551	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Pruritus; Rash	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Followed By 100 Qd;		Gilead
	Bimatoprost			C				Not Reported
	Brimonidine			C				Not Reported
	Budesonide-Formoterol			C				Not Reported

Buspirone	C	Not Reported
Phenytoin	C	Not Reported
Vitamin C	C	Not Reported
Meropenem	C	Not Reported
Vancomycin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106563	DIRECT	Y	LT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Haemodialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106575	DIRECT	Y	LT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Dialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106589	DIRECT	Y	LT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Dialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106601	DIRECT	Y	LT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

Aminotransferase Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106616	DIRECT	Y	OT			79 YR	Female	AFG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Vasopressin			C				Not Reported
	Simvastatin			C				Not Reported
	Phenylephrine (Infusion)			C				Not Reported
	Omeprazole			C				Not Reported
	Norepinephrine			C				Not Reported
	Hydrocortisone (Injection)			C				Not Reported
	Fentanyl (Infusion)			C				Not Reported
	Cefepime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106624	DIRECT	Y	OT			65 YR	Male	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106634	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoxia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18106673	DIRECT	Y	DE			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heparin-Induced Thrombocytopenia; Heparin-Induced Thrombocytopenia; Ischaemic Hepatitis; Renal Failure; Respiratory Distress	Remdesivir	Y		S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18107815	EXPEDITED (15-DAY)		DE, OT	US-SA-2020SA199688			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Fenofibrate			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Nph Insulin			C		Unk		Not Reported
	Insulin Human;Insulin Human Injection, Isophane			C		Unk		Not Reported
	Sodium Chloride			C		Unk		Not Reported
	Sitagliptin			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2020	18109310	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir	Y		S				Not Reported

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18026839	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482905		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Cardiac Arrest; Congestive Cardiomyopathy; Covid-19; Ischaemic Hepatitis; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Renal Failure; Sepsis; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Ascorbic			C				Not Reported
	Vitamin D3			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Novolog Mix			C				Not Reported
	Levemir			C				Not Reported
	Nitroglycerin Recip			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Lovenox Hp			C				Not Reported
	Ivermectin			C				Not Reported
	Dexamethasone			C				Not Reported
	Vitamin C + Zinc			C				Not Reported
	Plasma			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109336	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

		Hydrochlorothiazide 12.5mg Daily			C					Not Reported
		Losartan 100 Mg Daily			C					Not Reported
		Dexamethasone 6 Mg Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109342	DIRECT	Y	DE			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Electrolyte Imbalance; General Physical Health Deterioration; Glomerular Filtration Rate Decreased; Multiple Organ Dysfunction Syndrome; Pyrexia; Ventricular Tachycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109348	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported
	Cefepime Iv			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109353	DIRECT	Y	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir Eua Gs-5734	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

	Actemra 400 Mg Iv Once			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109386	DIRECT	Y				51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Continuous Haemodiafiltration; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Zemuron			C				Not Reported
	Versed			C				Not Reported
	Fentanyl			C				Not Reported
	Diprivan			C				Not Reported
	Vasostrict			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109389	DIRECT	Y	DS, HO			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebral Infarction	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109393	DIRECT	Y	OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Procalcitonin Increased	Remdesivir			S	Intravenous drip			Gilead
	Albuterol			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Heparin			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109395	DIRECT	Y	LT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip	Other Frequency:Once (Loading Dose);		Gilead
	Dexamethasone Injection			C				Not Reported
	Enoxaparin Injection			C				Not Reported
	Pantoprazole Injection			C				Not Reported
	Aspirin Ec Tablet			C				Not Reported
	Atorvastatin Tablet			C				Not Reported
	Clopidogrel Bisulfate Oral			C				Not Reported
	Losartan Oral			C				Not Reported
	Metoprolol Tartrate Oral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109398	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109402	DIRECT	Y	OT			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Acetaminophen 650 Mg Q4h Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109407	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109412	DIRECT	Y				54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema; Pain; Phlebitis; Tissue Infiltration	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109420	DIRECT	Y	DE			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardio-Respiratory Arrest; Creatinine Renal Clearance Decreased; General Physical Health Deterioration	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109426	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not			Gilead

							otherwise specified)			
		Azithromycin			C					Not Reported
		Ceftriaxone			C					Not Reported
		Dexamethasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109431	DIRECT	Y	LT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Haemodialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109435	DIRECT	Y				96 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109448	DIRECT	Y	DE			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Complication; Renal Failure	Remdesivir			S				Not Reported
	Precedex Continuous Infusion			C				Not Reported
	Fentanyl Continuous Infusion			C				Not Reported
	Insulin Continuous Infusion			C				Not Reported
	Ketamine Continuous Infusion			C				Not Reported
	Midazolam Continuous Infusion			C				Not Reported
	Propofol Continous Infusion			C				Not Reported
	Vasopressin Continous Infusion			C				Not Reported
	Norepinephrine Continous Infusion			C				Not Reported
	Aspirin 81 Mg Po Daily			C				Not Reported
	Cefazolin 1g Iv Q12h			C				Not Reported

	Heparin 5000 Units Sub Q Q12h	C		Not Reported
	Methylprednisolone 10 Mg Iv Q24h	C		Not Reported
	Nystatin 100,000 Units 2 Times Topically Daily	C		Not Reported
	Protonix 40 Mg Iv Q12h	C		Not Reported
	Quetiapine 400 Mg Po Bid	C		Not Reported
	Sodium Bicarb 1300 Mg 4x/Day Po	C		Not Reported
	Voriconazole 400 Mg Iv Q12h	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109455	DIRECT	Y	HO			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prerenal Failure	Remdesivir	Y		S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18109508	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0488639		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18111648	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0488736		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Remdesivir			S	Unknown	Unk		Gilead
	Compazine [Prochlorperazine Maleate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18112762	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18112774	DIRECT	Y	OT			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18112798	DIRECT	Y	OT			88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18112802	DIRECT	Y	OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18113464	DIRECT	Y	RI			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir 200mg			S	Intravenous (not otherwise specified)			Gilead
	Baricitinib			C				Not Reported
	Tylenol			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported
	Famotidine			C				Not Reported
	Insulin			C				Not Reported
	Ketorolac			C				Not Reported
	Miralax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2020	18118031	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Remdesivir 100 Mg Vials	Y		S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	17856483	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469863		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Unk			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	17876354	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469633		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Eliquis			C	Oral	2.5 Mg, Bid		Not Reported
	Eliquis			C		2.5 Mg, Bid		Not Reported
	Albuterol Hfa			C	Respiratory (inhalation)	Unk		Not Reported
	Amiodarone			C		200 Mg		Not Reported
	Amlodipine			C		5 Mg		Not Reported
	Atorvastatin			C		40 Mg		Not Reported
	Azithromycin			C		500 Mg		Not Reported
	Methylprednisolone			C		50 Mg		Not Reported
	Metoprolol Succinate			C		25 Mg		Not Reported
	Tocilizumab			C		400 Mg, Once		Not Reported
	Tocilizumab			C		200 Mg		Not Reported
	Pantoprazole			C		40 Mg		Not Reported
	Sodium Polystyrene Sulfonate			C		15 G		Not Reported
	Zinc Sulfate			C		220 Mg		Not Reported
	Nacl			C	Intravenous (not otherwise specified)	Prn		Not Reported
	Acetaminophen			C		650 Mg Prn		Not Reported
	Benzonatate			C		100 Mg Prn		Not Reported
	Melatonin			C		3 Mg Prn		Not Reported

	Ceftriaxone	C	1000 Mg	Not Reported
	Diphenhydramine	C	25 Mg	Not Reported
	Furosemide	C	40 Mg	Not Reported
	Levothyroxine	C	112 Mcg	Not Reported
	Oxygen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	17950432	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475638		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Unk		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Unk		Gilead
	Dopamine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Metoprolol			C				Not Reported
	Norepinephrine			C				Not Reported
	Vecuronium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112805	DIRECT	Y	DE			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Unresponsive To Stimuli	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Cefepime (Cefepime Hcl 2gm/Bag Inj)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112949	DIRECT	Y				50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Transaminases Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18112980	DIRECT	Y	RI			30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113334	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extravasation; Infusion Site Erythema; Infusion Site Extravasation	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113381	DIRECT	Y	RI			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Alkaline Phosphatase Increased; Blood Chloride Abnormal; Blood Creatine Abnormal; Blood Glucose Abnormal; Blood Potassium Abnormal; Blood Sodium	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

Abnormal; Blood Urea Abnormal; Eosinophil Count Abnormal; Haemoglobin Abnormal; Mean Cell Volume Abnormal; Platelet Disorder; Renal Disorder; White Blood Cell Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113435	DIRECT	Y	HO, RI, OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased; Therapy Interrupted	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18113521	DIRECT	Y	DE			89 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Respiratory Distress	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117859	DIRECT	N	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous drip			Gilead
	Asprin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported

	Chlorhexidine Topical	C	Not Reported
	Dexamethasone	C	Not Reported
	Docusate	C	Not Reported
	Famotidine	C	Not Reported
	Galatmaine	C	Not Reported
	Heparin	C	Not Reported
	Insulin Lispro	C	Not Reported
	Lactulose	C	Not Reported
	Loratadine	C	Not Reported
	Metronidazole	C	Not Reported
	Mupirocin	C	Not Reported
	Vancomycin	C	Not Reported
	Albumin	C	Not Reported
	Fentanyl	C	Not Reported
	Midazolam	C	Not Reported
	Propofol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117864	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cerebrovascular Accident; Dementia; Dyspnoea; Fibrin D Dimer Increased; Hyperlipidaemia; Hypertension; Pneumonia; Seizure; Troponin Increased; Type 2 Diabetes Mellitus	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117870	DIRECT	Y	OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased; Therapy Interrupted	Remdesivir	Y	S	Intravenous bolus	Gilead
	Acetaminophen Prn		C		Not Reported
	Atorvastatin		C		Not Reported
	Azithromycin		C		Not Reported
	Ceftriaxone		C		Not Reported
	Dexamethasone		C		Not Reported
	Duloxetine		C		Not Reported
	Enoxaparin		C		Not Reported
	Levothyroxine		C		Not Reported
	Losartan		C		Not Reported
	Metformin		C		Not Reported
	Pantoprazole		C		Not Reported
	Zolpidem		C		Not Reported
	Insulin Regular Sliding Scale		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117875	DIRECT	Y	DE			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Lexapro			C				Not Reported
	Dilauded			C				Not Reported
	Metaglip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117881	DIRECT	Y	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Infusion Related Reaction; Malaise	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesevir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117884	DIRECT	Y	OT			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amlodipine			C				Not Reported
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Lisinopril			C				Not Reported
	Dextromethorphan-Fuaifenesin			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117891	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117894	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117900	DIRECT	Y				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Ergocalciferol			C				Not Reported
	Rivaroxaban			C				Not Reported
	Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117905	DIRECT	Y				37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY	Not Reported
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Guaifenesin/Codeine			C				Not Reported
	Benadryl			C				Not Reported
	Lovenox			C				Not Reported
	Solumedrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117909	DIRECT	Y	DE			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117916	DIRECT	Y	DE			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Failure; Agitation; General Physical Health Deterioration; Mental Status Changes; Respiratory Failure	Remdesivir	S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117921	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Increased; Renal Impairment	Remdesivir			S				Not Reported
	Vancomycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Metronidazole			C				Not Reported
	Pip/Tazo			C				Not Reported
	Lovenox			C				Not Reported
	Dexamethasone			C				Not Reported
	Diltiazem			C				Not Reported
	Amiodarone			C				Not Reported
	Morphine			C				Not Reported
	Digoxin			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Levothyroxine			C				Not Reported
	Lansoprazole			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117926	DIRECT	Y	LT			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2020	18117929	DIRECT	Y	DE, LT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	17996062	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0480084		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cerebrovascular Accident; Oedema	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Heparin			C	Subcutaneous	5000unit		Not Reported
	Ascorbic Acid			C		500 Mg Tube		Not Reported
	Zinc			C		220 Mg Tube		Not Reported
	Cholecalciferol			C		5000 Unit Tube		Not Reported
	Dexamethasone			C		6 Mg Tube		Not Reported
	Nicardipine			C	Intravenous drip	Unk		Not Reported
	Amlodipine			C		5 Mg Tube		Not Reported
	Aspirin (E.C.)			C		81 Mg Tube		Not Reported
	Clopidogrel			C		75 Mg Tube		Not Reported
	Atorvastatin			C		40 Mg Tube		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	2 G		Not Reported
	Vancomycin [Vancomycin Hydrochloride]			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Docusate			C		100 Mg Tube		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Humalog			C	Subcutaneous	Scale		Not Reported

	Fentanyl			C	Intravenous drip	Unk			Not Reported
	Versed			C	Intravenous drip	Unk			Not Reported
	Norepinephrine			C	Intravenous drip	Unk			Not Reported
	Rocuronium			C	Intravenous drip	Unk			Not Reported
	Lantus			C	Subcutaneous	10 Unit			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18026374	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0482857		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Oxygen			C				Not Reported
	Escitalopram			C	Oral	10 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Dexamethasone			C	Oral	6 Mg		Not Reported
	Famotidine			C	Oral	20 Mg		Not Reported
	Lantus			C	Subcutaneous	Varies		Not Reported
	Toprol Xl			C		26 Mg		Not Reported
	Protonix			C	Oral	40 Mg		Not Reported
	Gabapentin			C		300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118316	DIRECT	Y				72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palliative Care; Therapy	Remdesivir			S				Not Reported

Cessation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18118960	DIRECT	Y	OT			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Benzonatate			C				Not Reported
	Codeine-Guaifenesin			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Levothyroxine			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18120142	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0488801		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Remdesivir			S	Unknown	100 Mg, Unk		Gilead
	Ceftriaxone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18121790	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489118		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122558	DIRECT	Y	OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol (Proair Hfa, Proventil Hfa, Ventolin Hfa) 108 (90 Base) Mcg/			C				Not Reported
	Budesonide/Formoterol (Symbicort) 80mcg/4.5mcg Oral Inhaler			C				Not Reported
	Dexamethasone (Decadron) 4mg/Ml Inj 4 Mg			C				Not Reported
	Enoxaparin (Lovenox) Inj 40 Mg			C				Not Reported
	Ipratropium (Atrovent Hfa) Oral Inhaler 2 Puff			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122561	DIRECT	Y	LT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122564	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Apap			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122568	DIRECT	Y	OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; International Normalised Ratio Increased; Liver Function Test Increased; Muscular Weakness	Remdesivir			S	Intravenous drip			Gilead
	Warfarin			S	Oral			Not Reported
	Atorvastatin			C				Not Reported
	Fluoxetine			C				Not Reported
	Trazodone			C				Not Reported
	Fluconazole			C				Not Reported
	Septra Iv			C				Not Reported
	Amiodarone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Naproxen			C				Not Reported
	Enoxaparin			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122589	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122590	DIRECT	Y				21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Cholecalciferol			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Methylprednisolone			C				Not Reported

		Acetaminophen			C						Not Reported
		Ondansetron			C						Not Reported
		Benzocaine-Menthol			C						Not Reported
		Sodium Chloride			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122591	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Prednisone			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122638	DIRECT	Y				38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122712	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Atenolol			C				Not Reported
	Azithromycin			C				Not Reported
	Calcium/Vitamin D			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Levothyroxine			C				Not Reported

		Magnesium Chloride Er			C					Not Reported
		Metformin			C					Not Reported
		Prednisone			C					Not Reported
		Acetaminophen Prn			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122715	DIRECT	Y				75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Issue	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122718	DIRECT	N					Prefer not to disclose	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122722	DIRECT	Y				48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Remdesivir			S				Not Reported
	Ceflriaxone			C				Not Reported
	Norco			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122724	DIRECT	Y				87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18122731	DIRECT	Y	HO			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous drip			Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18123264	DIRECT	Y	OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir Eua			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2020	18128621	DIRECT	Y				76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir 100mg	Y		S		Other Dose:D1 200mg;D2 5 100m;Other Route:Iv		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	17892214	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469666		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Proteinuria; Renal Tubular Necrosis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Azithromycin			C	Oral	500 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G		Not Reported
	Acetaminophen			C	Oral	650 Mg		Not Reported

Enoxaparin	C	Subcutaneous	30 Mg	Not Reported
Guaifenesin	C	Oral	200 Mg	Not Reported
Guaifenesin	C	Oral	200 Unk	Not Reported
Lactated Ringers	C	Intravenous (not otherwise specified)	Unk	Not Reported
Lokelma	C		10 G	Not Reported
Lokelma	C		10 Unk	Not Reported
Ns	C		500 Ml	Not Reported
Tocilizumab	C	Intravenous (not otherwise specified)	400 Mg	Not Reported
Albuterol;Ipratropium	C		2	Not Reported
Albuterol;Ipratropium	C		3	Not Reported
Etomidate	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Midazolam	C	Intravenous (not otherwise specified)	Unk	Not Reported
Rocuronium	C	Intravenous (not otherwise specified)	150 Mg	Not Reported
Atracurium	C	Intravenous (not otherwise specified)	Unk	Not Reported
Hydromorphone	C		Unk	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	2750 Mg	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	2250 Unk	Not Reported
Famotidine	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
Metoclopramide	C	Intravenous (not otherwise specified)	10 Mg	Not Reported

	Oxycodone			C	Oral	10 Mg			Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	Unk			Not Reported
	Bumetanide			C	Intravenous (not otherwise specified)	5 Mg			Not Reported
	Chlorothiazide			C	Intravenous (not otherwise specified)	1000 Mg			Not Reported
	Sodium Bicarbonate			C	Intravenous (not otherwise specified)	150 Meq			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18052350	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484228		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Tylenol			C		650 Mg		Not Reported
	Albuterol Hfa			C		Unk		Not Reported
	Ceftriaxone			C		1 G		Not Reported
	Ns			C		Unk		Not Reported
	Azithromycin			C		500 Mg		Not Reported
	Heparin			C	Subcutaneous	7500 Unit		Not Reported
	Dextromethorphan;Guaifenesin			C		20 Mg		Not Reported
	Levothyroxin			C		137 Mcg		Not Reported
	Ondansetron			C		4 Mg		Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18061654	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484374		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg, Once		Not Reported
	Azithromycin	C	Oral	500 Mg, Qd		Not Reported
	Ascorbic Acid	C	Oral	1000 Mg, Qd		Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G		Not Reported
	Diphenhydramine	C	Intravenous (not otherwise specified)	25 Mg, Once Stat		Not Reported
	Enoxaparin	C	Subcutaneous	60 Mg, Bid		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	60 Mg, Q6h		Not Reported
	Zinc Sulphate	C	Oral	220 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18123944	DIRECT	Y	DE			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Staphylococcal	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124278	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489206		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg Loading Dose		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18124323	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489163		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Decreased; Death; Renal Impairment	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	Unk		Gilead
	Vancomycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Metronidazole			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Lovenox Hp			C				Not Reported
	Dexamethasone			C				Not Reported
	Diltiazem			C				Not Reported
	Amiodarone			C				Not Reported
	Morphine			C				Not Reported
	Digoxin			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Levothyroxine			C				Not Reported
	Lansoprazole			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18125132	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0489134		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Benzonatate			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

Dexamethasone	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Guaifenesin	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Acetaminophen	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18125628	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489269		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Malaise	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128216	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128221	DIRECT	Y				38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128225	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Blood Creatinine Increased; Covid-19 Pneumonia; Diabetes Mellitus; Inflammatory Marker Increased; Sars-Cov-2 Test Positive	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)		Gilead
	Albuterol	C			Not Reported
	Alprazolam	C			Not Reported
	Ascorbic Acid	C			Not Reported
	Aspirin	C			Not Reported
	Atorvastatin	C			Not Reported
	Cholecalciferol	C			Not Reported
	Famotidine	C			Not Reported
	Fluticasone	C			Not Reported
	Heparin	C			Not Reported
	Insulin Glargine	C			Not Reported
	Insulin Lispro	C			Not Reported
	Lisinopril	C			Not Reported
	Ivermectin	C			Not Reported
	Azithromycin	C			Not Reported
	Dexamethasone	C			Not Reported
	Ceftriaxone	C			Not Reported
	Metformin	C			Not Reported
	Methylprednisolone	C			Not Reported
	Pantoprazole	C			Not Reported
	Thiamin	C			Not Reported
	Zinc Gluconate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128257	DIRECT	Y	OT			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous bolus			Gilead
	Betamethasone			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cephalexin			C				Not Reported
	Aspririn			C				Not Reported
	Cholecalciferol			C				Not Reported
	Heparin			C				Not Reported
	Metronidazole			C				Not Reported

		Prenatal Vitamin			C					Not Reported
		Zinc Sulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128295	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Remdesivir Lyophilized Powder	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128301	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128305	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amoxil 875mg			C				Not Reported
	Azithromycin 250mg			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Decadron			C				Not Reported
	Lovenox			C				Not Reported
	Pepcid			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128311	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous drip			Gilead
	Cefipime			C				Not Reported
	Lipitor			C				Not Reported
	Dexamehasone			C				Not Reported
	Furosemide			C				Not Reported
	Midazolam			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128315	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Chest X-Ray Abnormal; General Physical Health Deterioration; Oxygen Saturation Decreased	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128318	DIRECT	Y	OT			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128321	DIRECT	Y	HO, LT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Failure; Blood Lactic Acid Increased; Dialysis; Hypoxia; Lactic Acidosis; Renal Injury; Shock	Remdesivir 100mg Iv In 100ml Ns	Y		S	Intravenous drip				Gilead
	Vasopressin			C					Not Reported
	Norepinepherine			C					Not Reported
	Epinepherine			C					Not Reported
	Phenylephrine			C					Not Reported
	Angiotensin Ii			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128324	DIRECT	Y				37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128331	DIRECT	Y				72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128336	DIRECT	Y	HO			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal	Remdesivir			S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir			S	Intravenous drip		1 DAY	Gilead
	Albuterol Hfa			C				Not Reported
	Allopurinol 300mg			C				Not Reported
	Atorvastatin 40mg			C				Not Reported
	Azithromycin 500mg			C				Not Reported
	Budesonide Inhalation			C				Not Reported
	Calitriol 0.25mcg			C				Not Reported
	Ceftriaxone 2gm			C				Not Reported

		Dexamethasone 6mg			C					Not Reported
		Doxazosin 4mg			C					Not Reported
		Doxycycline 100mg			C					Not Reported
		Enoxaparin 40mg			C					Not Reported
		Heparin 5000 Units			C					Not Reported
		Insulin Lispro			C					Not Reported
		Duoneb			C					Not Reported
		Montelukast			C					Not Reported
		Pantoprazole 40mg			C					Not Reported
		Potassium 20meq			C					Not Reported
		Sodium Bicarb Tablets			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128345	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128349	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128956	DIRECT	Y	LT			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Fibrillation; Tachycardia	Remdesivir 200mg			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead

	Ibuprofen	C		Not Reported
	Diphenhydramine	C		Not Reported
	Albuterol	C		Not Reported
	Acetaminophen	C		Not Reported
	Sodium Chloride	C		Not Reported
	Sodium Chloride With Kci	C		Not Reported
	Ondansetron	C		Not Reported
	Heparin Flush	C		Not Reported
	Remdeivir	C		Not Reported
	Lidocaine-Tetracaine	C		Not Reported
	Lidocaine Pf	C		Not Reported
	Procainamide	C		Not Reported
	Papaverine	C		Not Reported
	Heparin	C		Not Reported
	Enoxaparin	C		Not Reported
	Diltiazem	C		Not Reported
	Adenosine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2020	18128992	DIRECT		OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	17883340	EXPEDITED (15-DAY)		DE, HO, OT	US-SA-2020SA148347			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Fenofibrate			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported

	Nph Insulin	C	Unk	Not Reported
	Sodium Chloride	C	Unk	Not Reported
	Sitagliptin	C	Unk	Not Reported
	Midazolam	C	Unk	Not Reported
	Pantoprazole	C	Unk	Not Reported
	Humuline	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18128395	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus		5 DAY	Gilead
	Ceftriaxone			C				Not Reported
	Zithromax			C				Not Reported
	Albuterol			C				Not Reported
	Decadron			C				Not Reported
	Lovenox			C				Not Reported
	Hydrocortisone (Perianal)			C				Not Reported
	Humalog			C				Not Reported
	Nph Insulin			C				Not Reported
	Protonix			C				Not Reported
	Sodium Chloride Nasal Spray			C				Not Reported
	Flomax			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Tylenol Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2020	18128400	DIRECT		OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Spasms; Respiratory Disorder; Tardive Dyskinesia; Tongue Spasm	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Levothyroxine			C				Not Reported
	Norvasc			C				Not Reported
	Benicar			C				Not Reported

		Glucophage			C					Not Reported
		Hydrocortisone			C					Not Reported
		Xyzal			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2020	18128356	DIRECT	Y				66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexmedetomidine			C				Not Reported
	Heparin			C				Not Reported
	Metronidazole			C				Not Reported
	Sodium Phosphate			C				Not Reported
	Doxycycline			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Methylprednisolone			C				Not Reported
	Metoprolol			C				Not Reported
	1/4 Normal Saline			C				Not Reported
	Vancomycin Enema			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2020	18128404	DIRECT	Y	DE			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dialysis; Multiple Organ Dysfunction Syndrome; Paralysis; Transaminases Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2020	18129570	DIRECT	Y	OT			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir	S	Intravenous drip		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18010203	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0481436		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg		Not Reported
	Dexamethasone			C	Oral	6 Unk		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Ondansetron			C	Intravenous (not otherwise specified)	4 Mg		Not Reported
	Ondansetron			C				Not Reported
	Acetaminophen			C		Unk		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18061063	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484797		91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir			S	Intravenous (not	200 Mg, Once		Gilead

Increased; Aspartate Aminotransferase Increased; Death	otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18125998	EXPEDITED (15-DAY)		HO, OT	CH-ABBVIE-20K-151-3512526-00		30 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Colitis; Condition Aggravated; Hypercholesterolaemia; Hypertriglyceridaemia; Lipase Increased; Off Label Use; Pancreatitis; Renal Impairment; Staphylococcal Infection	Kaletra			S	Oral	Morning, Evening		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Disoprivan			S	Intravenous (not otherwise specified)			Not Reported
	Disoprivan			S	Intravenous drip			Not Reported
	Disoprivan			S	Intravenous drip			Not Reported
	Disoprivan			S	Intravenous drip			Not Reported
	Remdesivir			S	Unknown			Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)			Not Reported
	Midazolam			C	Intravenous (not otherwise specified)			Not Reported
	Co-Amoxicillin			C	Intravenous (not otherwise specified)	Morning, Noon, Evening		Not Reported
	Tazobac [Piperacillin Sodium; Tazobactam Sodium]			C	Intravenous (not otherwise specified)	Morning, Noon, Evening		Not Reported
	Hydroxychloroquine Zentiva			C	Oral			Not Reported
	Hydroxychloroquine Zentiva			C	Oral			Not Reported
	Konakion			C	Intravenous (not otherwise specified)	Morning, Evening		Not Reported
	Primperan			C	Oral	Morning, Evening		Not Reported
	Nexium [Esomeprazole Magnesium]			C	Oral	Morning		Not Reported
	Vancomycin			C	Oral	Morning, Noon, Evening,		Not Reported

							Night			
	Fragmin			C			At Night			Not Reported
	Gevilon			C	Oral					Not Reported
	Gevilon			C	Oral					Not Reported
	Fish Oil			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18128384	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18128442	DIRECT	Y	DE, HO			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Aspartate Aminotransferase Increased; Blood Lactic Acid Increased; Cardiac Arrest; Chest Pain; Electrocardiogram St Segment Elevation; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Thrombosis	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Levetiracetam			C				Not Reported
	Lactulose			C				Not Reported
	Omeprazole			C				Not Reported
	Rifaximin			C				Not Reported
	Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130079	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

	Dexamethasone 6mg Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130086	DIRECT	Y				82 YR	Male	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Levofloxacin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130119	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S				Not Reported
	Acyclovir			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130124	DIRECT	Y	OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S			4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130129	DIRECT	Y	DE			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pulseless Electrical Activity; Respiratory Failure; Sepsis	Remdesivir	Y	S	Intravenous bolus	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130132	DIRECT	Y	HO			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency: 200mgx1,100mg/Dx4;		Gilead
	Acetaminophen 650mg Po Q6h Prn Pain 1-3			C				Not Reported
	Albuterol Hfa 2 Puff Inh Q4h And Q6h Prn			C				Not Reported
	Amiodarone Bolus And Infusion			C				Not Reported
	Apixaban 5mg Po Bid			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Cefepime 1g Iv Q8h			C				Not Reported
	Precedex Infusion			C				Not Reported
	Cardizem Cd 120mg Po Daily			C				Not Reported
	Diltiazem Infusion			C				Not Reported
	Famotidine 20mg Iv Q12h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Folic Acid 1mg Po Daily			C				Not Reported
	Gabapentin 300mg Po Tid			C				Not Reported
	Heparin Infusion			C				Not Reported
	Lantus Subq Qhs			C				Not Reported
	Insulin Lispro Sliding Scale 4x/Day			C				Not Reported
	Meropenem			C				Not Reported
	Methimazole			C				Not Reported
	Methylprednisolone 60mg Q6h			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130133	DIRECT		DE			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Respiratory Failure	Remdesivir	Y	S	Intravenous (not otherwise specified)	Not Reported
	Vitamin C		C		Not Reported
	Zinc Gluconate		C		Not Reported
	Sertraline		C		Not Reported
	Pantoprazole		C		Not Reported
	Lorazepam		C		Not Reported
	Insulin Regular		C		Not Reported
	Insulin Lispro		C		Not Reported
	Furosemide		C		Not Reported
	Colchicine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130144	DIRECT		OT			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Liver Function Test Increased; Oxygen Saturation Decreased; Somnolence	Remdesivir	Y		S				Not Reported
	Vitamin C			C				Not Reported
	Zinc			C				Not Reported
	Pantoprazole			C				Not Reported
	Insulin Lispro			C				Not Reported
	Enoxaparin			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Divalproex Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130145	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130186	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin 1000 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130187	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Hydromorphone			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Epoprostenol Nebulizer Continuous			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130231	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency: 200mgx1,100mgx4;		Gilead
	Atorvastatin 20mg Po Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Benzonatate 200mg Po Q8h			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Dexamethasone 10mg Iv Daily			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Culturelle 1 Cap Po Tid			C				Not Reported
	Levothyroxine 112mcg Po Daily			C				Not Reported
	Losartan 50mg Po Daily			C				Not Reported

	Metoprolol Succinate 25mg Po Daily	C		Not Reported
	Vitamin C 1000mg Po Daily	C		Not Reported
	Zinc Sulfate 220mg Po Daily	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18130864	EXPEDITED (15-DAY)			US-GILEAD-2020-0489320			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18131652	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489308		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18134672	DIRECT	Y				68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Pancuronium			C				Not Reported
	Insulin			C				Not Reported
	Pantoprazole			C				Not Reported
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Lorazepam			C				Not Reported
	Morphine			C				Not Reported

	Ceftriaxone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18134675	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported
	Cilostazol			C				Not Reported
	Furosemide			C				Not Reported
	Isosorbide			C				Not Reported
	Norepinephrine			C				Not Reported
	Ranolazine			C				Not Reported
	Metoprolol			C				Not Reported
	Aspirin			C				Not Reported
	Hydrocodone-Acetaminophen			C				Not Reported
	Fentanyl			C				Not Reported
	Rocuronium			C				Not Reported
	Clopidogrel			C				Not Reported
	Enoxaparin			C				Not Reported
	Heparin			C				Not Reported
	Omeprazole			C				Not Reported
	Sucralfate			C				Not Reported
	Fesoterodine			C				Not Reported
	Dexamethasone			C				Not Reported
	Atorvastatin			C				Not Reported
	Insulin			C				Not Reported
	Vitamin C			C				Not Reported
	Mag-Ox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18134703	DIRECT	Y	DE			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Oxygen Saturation Decreased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18134716	DIRECT	Y	HO			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18134719	DIRECT	Y	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Sublimaze			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18134731	DIRECT	Y	HO			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous drip			Gilead
	Atorvastatin			C				Not Reported
	Zosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2020	18134741	DIRECT	Y				29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Tylenol			C				Not Reported
	Azithromycin			C				Not Reported

	Ceftriaxone			C						Not Reported
	Dexamethsone			C						Not Reported
	Enoxaparin			C						Not Reported
	Pepcid			C						Not Reported
	Furosemide 20mg			C						Not Reported
	Loperamide			C						Not Reported
	Guaifenesin			C						Not Reported
	Milk Of Magnesia			C						Not Reported
	Ondansetron			C						Not Reported
	Miralax			C						Not Reported
	Simethicone			C						Not Reported
	Zolpidem			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18001041	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0480947		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ammonia Increased; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			S	Intravenous (not otherwise specified)	2 G, Once		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	1250 Mg, Tid		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Levophed			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pantoprazole			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Atorvastatin			C				Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Albumin			C				Not Reported

Thiamine	C	Oral	100 Mg, Bid	Not Reported
Lasix [Furosemide]	C	Intravenous (not otherwise specified)	20 Mg, Bid	Not Reported
Lantus	C			Not Reported
Multivitamin With Minerals	C	Oral	Unk, Qd	Not Reported
Ezetimibe	C			Not Reported
Hydrochlorothiazide;Irbesartan	C			Not Reported
Isosorbide Mononitrate	C	Oral	30 Mg, Qd	Not Reported
Tamsulosin	C			Not Reported
Ceftriaxone	C			Not Reported
Enoxaparin	C	Subcutaneous	40 Mg	Not Reported
Enoxaparin	C	Subcutaneous	90 Mg	Not Reported
Azithromycin	C	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	2 G, Q8h	Not Reported
Fentanyl	C	Intravenous (not otherwise specified)	Unk	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Midazolam	C	Intravenous (not otherwise specified)	Unk	Not Reported
Vasopressin	C		Unk	Not Reported
Lactulose	C	Oral	20 Mg, Tid	Not Reported
Lactulose	C	Oral	20 Mg, Q6h	Not Reported
Lactulose	C	Oral	30 Mg, Q4hr	Not Reported
Nimbex [Nimesulide]	C	Intravenous (not otherwise specified)	Unk	Not Reported
Linezolid	C	Intravenous (not otherwise specified)	600 Mg, Bid	Not Reported
Meropenem	C	Intravenous (not otherwise specified)	1 G, Bid	Not Reported
Hydrocortisone	C	Intravenous (not otherwise specified)	50 Mg, Q6h	Not Reported

	Amiodarone		C	Intravenous (not otherwise specified)	Unk	Not Reported
	Heparin		C	Intravenous (not otherwise specified)	Unk	Not Reported
	Rifaximin		C	Oral	550 Mg, Bid	Not Reported
	Phenylephrine		C			Not Reported
	Micafungin		C			Not Reported
	Sodium Bicarbonate		C			Not Reported
	Oxygen		C			Not Reported
	Ascorbic Acid		C	Oral	500 Mg	Not Reported
	Norepinephrine		C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18057091	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484405		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd (No Dose Received 17-Jul-2020		Gilead
	Acetaminophen			C		Unk		Not Reported
	Amlodipine			C	Oral	5 Mg		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg		Not Reported
	Dexmedetomidine			C	Intravenous (not otherwise specified)	Unk, Titrate		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk, Titrate		Not Reported

	Midazolam	C	Intravenous (not otherwise specified)	Unk, Titrate		Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	Unk, Titrate		Not Reported
	Propofol	C	Intravenous (not otherwise specified)	Unk, Titrate		Not Reported
	Vasopressin	C	Intravenous (not otherwise specified)	Unk, Titrate		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18133801	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020299356			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Transplacental	Unk		Pfizer
	Magnesium Sulfate			S	Transplacental	Unk		Pfizer
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Betamethasone			S	Transplacental	1 Dose Of Betamethasone 4 Hours Prior To Delivery		Not Reported
	Tocilizumab			S	Transplacental	Unk		Not Reported
	Nitric Oxide			S	Transplacental	Inhaled		Not Reported
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135081	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489534		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Albuterol Hfa			C				Not Reported
	Symbicort			C				Not Reported
	Decadron A			C				Not Reported

		Lovenox Hp			C					Not Reported
		Atrovent Hfa			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135497	DIRECT	Y				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Infusion Site Swelling; Paravenous Drug Administration	Eua Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Eculizumab			C				Not Reported
	Decadron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135500	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135503	DIRECT	Y	HO, OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Atrial Fibrillation; Blood Alkaline Phosphatase Increased; Cardiac Arrest; Cytokine Storm; Inflammatory Marker Increased	Remdesivir			S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135515	DIRECT	Y				77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once, Then 100mgqd;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135522	DIRECT	Y	HO			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135523	DIRECT	Y	DE			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Disease Progression	Remdesivir	Y		S				Gilead
	Dexamethasone			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Chlorhexidine			C				Not Reported
	Digoxin			C				Not Reported
	Furosemide			C				Not Reported
	Lactobacillus			C				Not Reported
	Melatonin			C				Not Reported
	Vancomycin			C				Not Reported
	Tizanidine			C				Not Reported
	Sucralfate			C				Not Reported
	Scopolamine Patch			C				Not Reported
	Polyethlene Glycol			C				Not Reported
	Morphine			C				Not Reported
	Metoprolol Tartrate			C				Not Reported

		Meropenem			C					Not Reported
		Hyoscyamine			C					Not Reported
		Hydromorphone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135524	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135525	DIRECT	Y	DE			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Mental Disorder	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135528	DIRECT					46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	0.9% Sodium Chloride 100ml			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18135530	DIRECT	Y	DE			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cardio-Respiratory Arrest; Covid-	Remdesivir			S	Intravenous (not			Gilead

19 Pneumonia; Drug Ineffective	otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18136209	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2020-022396		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal	Dexametasona			S	Intravenous (not otherwise specified)	(722a), 6 Mg C/24		Bausch And Lomb
	Dexametasona			S				Bausch And Lomb
	Hidroxicloroquina			S	Oral	(2143a), 400 Mg C/12 Hr Dc Y 200 Mg C/12 Maintenance		Not Reported
	Hidroxicloroquina			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram/24 Hr (501a)		Not Reported
	Ceftriaxona			S				Not Reported
	Remdesivir			S	Intravenous drip	(10009a), 100 Mg C/24h		Not Reported
	Remdesivir			S				Not Reported
	Azitromicina			S	Oral	(7019a) 500 Mg, Shock Dose And 250 Mg C/24 Hr Maintenance		Not Reported
	Azitromicina			S				Not Reported
	Midazolam			C		2256a		Not Reported
	Fentanilo			C		1543a		Not Reported
	Enoxaparina			C		2482a		Not Reported
	Cisatracurio			C		2738a		Not Reported
	Paracetamol			C		12a		Not Reported
	Omeprazol			C		2141a		Not Reported
	Enalapril			C		2142a		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18137785	EXPEDITED (15-DAY)			US-GILEAD-2020-0489525			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18137792	EXPEDITED (15-DAY)			US-GILEAD-2020-0489540			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138493	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138499	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Acetaminophen			C				Not Reported
	Hydralazine			C				Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Buproprion			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Pantoprazole			C				Not Reported
	Prednisone			C				Not Reported

	Sertraline			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138506	DIRECT	Y	OT			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir For Eua			S	Intravenous (not otherwise specified)			Gilead
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138512	DIRECT	Y				51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138550	DIRECT	Y				51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dyspepsia; Liver Function Test Increased; Nausea; Vomiting	Eua Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported
	Tylenol			C				Not Reported
	Zofran			C				Not Reported
	Tigan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138579	DIRECT	Y	DE			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapy Cessation	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	S	Intravenous (not otherwise specified)			Gilead
	Morphine	C				Not Reported
	Loratadine	C				Not Reported
	Lisinopril	C				Not Reported
	Levalbuterol	C				Not Reported
	Ipratroipium	C				Not Reported
	Tussionex	C				Not Reported
	Proscar	C				Not Reported
	Enoxaparin	C				Not Reported
	Doxycycline	C				Not Reported
	Dexamethasone	C				Not Reported
	Ceftriaxone	C				Not Reported
	Pulmicort	C				Not Reported
	Benzonatate	C				Not Reported
	Aspirin Low Dose	C				Not Reported
	Alprazolam	C				Not Reported
	Albuterol Inhaler	C				Not Reported
	Acetaminophen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138585	DIRECT	Y				51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Nausea; Vomiting	Eua Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported
	Tylenol			C				Not Reported
	Zofran			C				Not Reported
	Tigan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138598	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Use In Unapproved Indication	Remdesivir	S		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138657	DIRECT	Y				45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138660	DIRECT	Y	OT			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir For Injection 100 Mg/Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Albuterol Inhaler			C				Not Reported
	Ascorbic Acid 500mg Tab			C				Not Reported
	Cholecalciferol 2000 Unit Cap			C				Not Reported
	Dexamethasone Gmg Tab			C				Not Reported
	Enoxaparin 40mg Inj			C				Not Reported
	Zinc Sulfate 220mg Cap			C				Not Reported
	Guaifenesin 600mg Tab			C				Not Reported
	Ipratropium Neb			C				Not Reported
	Docusate Sodium 200mg Cap			C				Not Reported
	Temazepam 30mg Cap			C				Not Reported
	Senna 17.2mg Cap			C				Not Reported
	Aluminum/Magnesium Hydroxide			C				Not Reported
	Lidocaine Viscous			C				Not Reported
	Simethicone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138678	DIRECT		OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrioventricular Block Second Degree; Electrocardiogram T Wave Abnormal; Fibrin D Dimer Increased; Sinus Arrhythmia; Sinus Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138825	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138827	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138830	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138836	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138841	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138855	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138862	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138867	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138870	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138873	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138877	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138882	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138889	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138895	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138898	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138901	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138905	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138925	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138931	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138932	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138935	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138940	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138945	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138952	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138958	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138962	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138986	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138991	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18138996	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18139002	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18139092	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2020	18139096	DIRECT	N					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18059208	EXPEDITED (15-DAY)			US-GILEAD-2020-0484718			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Product Administration Duration	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18061107	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484795		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dimethicone			C				Not Reported
	Aztreonam			C	Intravenous (not otherwise specified)	2000 Mg		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	20 Mg		Not Reported

	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139116	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Decreased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:X1;		Gilead
	Albuterol			C				Not Reported
	Atenolol			C				Not Reported
	Azithromycin			C				Not Reported
	Budesonide			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Montelukast			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D3			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139382	DIRECT	Y	DE			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Doxycycline			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139397	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139402	DIRECT	Y				88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Doxycycline			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139427	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139444	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139448	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139450	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139512	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139514	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139720	DIRECT	Y	DE			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Bilvarudin			C				Not Reported
	Escitalopram			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin			C				Not Reported
	Levothyroxine			C				Not Reported
	Metformin			C				Not Reported
	Norepinephrine			C				Not Reported
	Omeprazole			C				Not Reported
	Propofol			C				Not Reported

	Rampiril			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139990	DIRECT	Y				87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atenolol 25 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18139992	DIRECT	Y				81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140064	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140068	DIRECT	Y				39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140069	DIRECT	Y				80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S				Gilead
	Toprol Xl 100 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140088	DIRECT	Y				79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atenolol 50 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140232	DIRECT		OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S			1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140238	DIRECT	Y				30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140240	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140243	DIRECT	Y	OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Eua Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ketorolac			C				Not Reported
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140247	DIRECT	Y				53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140252	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Lopressor 25 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140256	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Toprol Xl 50 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140289	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140295	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Toprol Xl 50 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140300	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140397	DIRECT	Y				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Toprol Xl 50 Mg			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140403	DIRECT	Y				55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Toprol Xl 50 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140407	DIRECT	Y				70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140411	DIRECT	Y				78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18140416	DIRECT	Y				38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18141502	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0489784		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Lactic Acidosis; Renal Injury; Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142347	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489770		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Bacteraemia; Bacteraemia; Death; Hypotension; Klebsiella Bacteraemia; Pulmonary Embolism; Shock; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Dexamethasone			C		Unk		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Infusion		Not Reported
	Epoprostenol			C	Respiratory (inhalation)	Unk		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Infusion		Not Reported
	Cisatracurium			C	Intravenous (not otherwise specified)	Infusion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18142375	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489676		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Exposure During Pregnancy; Transaminases Increased	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Betamethasone	C				Not Reported
	Dexamethasone	C				Not Reported
	Ceftriaxone	C				Not Reported
	Cephalexin Amel	C				Not Reported
	Aspirin (E.C.)	C				Not Reported
	Heparin	C				Not Reported
	Metronidazole	C				Not Reported
	Zinc Sulfate	C				Not Reported
	Prenatal Vitamins [Minerals Nos; Vitamins Nos]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18143328	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489776		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144179	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144185	DIRECT	Y				87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atenolol 50 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144194	DIRECT	Y				68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144201	DIRECT	Y	OT			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Eua Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Eculizumab			C				Not Reported
	Eculizumab			C				Not Reported
	Eculizumab			C				Not Reported
	Decadron			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Rilpivirine			C				Not Reported
	Prezcobix			C				Not Reported
	Singulair			C				Not Reported
	Enoxaparin			C				Not Reported
	Dolutegravir			C				Not Reported
	Cholecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144207	DIRECT		DE			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cough; Dyspnoea; Hyperglycaemia; Malaise;	Remdesivir	Y		S	Intravenous bolus			Not Reported
	Convalescent Plasma			C				Not Reported
	Dexamethasone			C				Not Reported
	Tocilizumab			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported

Pyrexia; Respiratory Failure; Serum Ferritin; White Blood Cell Count Increased	Enoxaparin			C					Not Reported
	Hycodan			C					Not Reported
	Hydromorphone			C					Not Reported
	Meropenem			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144249	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Albuterol Inhaler			C				Not Reported
	Amlodipine			C				Not Reported
	Benzonatate			C				Not Reported
	Bismuth Subsalicylate			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin Dextromethorphan			C				Not Reported
	Hydralazine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Ipratropium Albuterol			C				Not Reported
	Lorazepam			C				Not Reported
	Ondansetron			C				Not Reported
	Prochlorperazine			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144256	DIRECT	Y	HO			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Creatinine Renal Clearance Increased	Remdesivir			S	Intravenous bolus			Gilead
	Symbicort			C				Not Reported
	Nimbex			C				Not Reported
	Lovenox			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Duo-Neb			C				Not Reported
	Methylprednisolone			C				Not Reported
	Propofol			C				Not Reported
	Quetiapine			C				Not Reported

		Venlafaxine			C					Not Reported
		Vitamin D			C					Not Reported
		Zinc Sulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144262	DIRECT	Y	OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Ibuprofen			C				Not Reported
	Melatonin			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144269	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Dexamethasone 6 Mg Ivp			C				Not Reported
	Acetaminophen 1000 Mg Ivpb			C				Not Reported
	Enoxaparin 40 Mg Subcut			C				Not Reported
	Lorazepam 1 Mg Ivp			C				Not Reported
	Midazolam 5-10 Mg Intranasal			C				Not Reported
	Nystatin Topical Powder			C				Not Reported
	Phenobarbital 150 Mg Ivpb			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144274	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir	Y	S	Intravenous drip		Not Reported
	Remdesivir	Y	S	Intravenous drip		Not Reported
	Aspirin 81 Mg Daily		C			Not Reported
	Atorvastatin 40 Mg Daily		C			Not Reported
	Decadron 6 Mg Daily		C			Not Reported
	Heparin 5000 Units Sq Q 8hr		C			Not Reported
	Lisinopril 10 Mg Daily		C			Not Reported
	Tylenol 500 Mg Q 6 Hr Prn		C			Not Reported
	Cepacol Lozenge 1 Lozenge Prn		C			Not Reported
	Robitussin 200 Mg Q 4hr Prn Cough		C			Not Reported
	Duoneb Nebulizer Q 6hr Prn		C			Not Reported
	Zofran 4mg Iv Q 6hr Prn		C			Not Reported
	Pantoprazol 40 Mg Daily		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144306	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atrial Fibrillation; Cardiac Arrest; General Physical Health Deterioration; Hypoxia; Ischaemic Hepatitis; Multiple Organ Dysfunction Syndrome; Pulseless Electrical Activity; Renal Failure	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Not Reported
	Remdesivir			S	Intravenous bolus			Not Reported
	Calcium Gluconate Ivpb			C				Not Reported
	Sodium Bicarbonate Iv			C				Not Reported
	Atracurium Iv			C				Not Reported
	Bisacodyl 10mg Suppository			C				Not Reported
	Cefepime Iv			C				Not Reported
	Decadron			C				Not Reported
	Lovenox Sq			C				Not Reported
	Furosemide Iv			C				Not Reported
	Midazolam Iv			C				Not Reported
	Multivitamin/Mineral Liq (Centrum)			C				Not Reported
	Protonix Iv			C				Not Reported
	Sodium Polystyrene Sulfonate Liq Ng			C				Not Reported
	Apresoline Iv			C				Not Reported
	Heparin Iv			C				Not Reported
	Hydromorphone Iv			C				Not Reported
	Levophed Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2020	18144857	DIRECT	Y	DE			15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Disease Progression; General Physical Health Deterioration; Protein Urine Present; Renal Failure; Renal Impairment; Respiratory Failure; Therapy Non-Responder; Urine Output Decreased	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144801	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144802	DIRECT	Y	OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144820	DIRECT	Y	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir	Y		S	Intravenous drip			Gilead

Increased; Liver Function Test Increased; Therapy Cessation	Dexamethasone			C					Not Reported
	Enoxaparin			C					Not Reported
	Ceftriaxone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144821	DIRECT	Y				36 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Candidiasis	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone 6mg			C				Not Reported
	Vitamin C 500mg			C				Not Reported
	Albuterol 1.25mg			C				Not Reported
	Enoxaparin 50mg			C				Not Reported
	Furosemide 20mg			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lisinopril 10mg			C				Not Reported
	Melatonin 10mg			C				Not Reported
	Thiamine 100mg			C				Not Reported
	Zinc Sulfate 220mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144855	DIRECT	Y				82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144860	DIRECT	Y	OT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip		2 DAY	Gilead
	Acetaminophen			C				Not Reported
	Carbamazepine			C				Not Reported
	Dexamethasone			C				Not Reported

	Zosyn			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18144862	DIRECT	Y				75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Renal Tubular Necrosis; Therapy Interrupted	Remdesivir	Y		S	Intravenous drip			Gilead
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Lantus			C				Not Reported
	Lactobaccilus			C				Not Reported
	Mvi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18145290	DIRECT	Y	OT			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 10mg Iv Bid			C				Not Reported
	Enoxaparin 40mg Subcutaneous Q12h			C				Not Reported
	Azithromycin 500mg Iv			C				Not Reported
	Ceftriaxone 1gm Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18145348	DIRECT	Y	DE, HO			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18145814	EXPEDITED (15-DAY)		LT, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2020VAL000659			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Kidney Injury; Atrial Fibrillation; Blood Pressure Increased; Ecchymosis; Fungaemia; Generalised Oedema; Hypotension; Oral Herpes; Pneumonia Bacterial; Toxic Encephalopathy	Bumex			S	Unknown	Unk		Validus
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Linezolid			S	Unknown	600 Mg, Bid		Not Reported
	Linezolid			S				Not Reported
	Meropenem			S	Unknown	500 Mg, Every 6 Hour		Not Reported
	Meropenem			S				Not Reported
	Acyclovir /00587301/			S	Unknown	Unk		Not Reported
	Anidulafungin			S	Unknown	Unk		Not Reported
	Vitamin B Complex			C		Unk		Not Reported
	Ocuvite /01053801/			C		Unk		Not Reported
	Coq10 /08485401/			C		Unk		Not Reported
	Multivitamin /07504101/			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Aspirin /00002701/			C		Unk		Not Reported
	Repatha			C		Unk		Not Reported
	Valsartan			C		Unk		Not Reported
	Dexilant			C		Unk		Not Reported
	Androgel			C		Unk		Not Reported
	Jardiance			C		Unk		Not Reported

Bystolic	C	Unk	Not Reported
Hydroxychloroquine	C	Unk	Not Reported
Azithromycine	C	Unk	Not Reported
Augmentin /00852501/	C	Unk	Not Reported
Tracrium	C	Unk	Not Reported
Cefepime	C	Unk	Not Reported
Protonix /00661201/	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Versed	C	Unk	Not Reported
Dilaudid	C	Unk	Not Reported
Acetaminophen	C	Unk	Not Reported
Lispro Insulin	C	Unk	Not Reported
Zinc	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported
Actemra	C	Unk	Not Reported
Thiamine	C	Unk	Not Reported
Docusate Sodium	C	Unk	Not Reported
Zemuron	C	Unk	Not Reported
Ascorbic Acid	C	Unk	Not Reported
Calcium Gluconate	C	Unk	Not Reported
Albumin	C	Unk	Not Reported
Melatonin	C	Unk	Not Reported
Ativan	C	Unk	Not Reported
Cefipime	C	Unk	Not Reported
Lovenox	C	Unk	Not Reported
Lasix /00032601/	C	Unk	Not Reported
Amidate /00466802/	C	Unk	Not Reported
Hydromorphone	C	Unk	Not Reported

Midazolam	C	Unk	Not Reported
Levophed	C	Unk	Not Reported
Phoxilium	C	Unk	Not Reported
Chlorhexidine	C	Unk	Not Reported
Insulin Detemir	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Sennosides A&B	C	Unk	Not Reported
Levemir	C	Unk	Not Reported
Sodium Phosphate	C	Unk	Not Reported
Reglan /00041901/	C	Unk	Not Reported
Tylenol /00020001/	C	Unk	Not Reported
Diovan	C	Unk	Not Reported
Tocilizumab	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Pepcid /00706001/	C	Unk	Not Reported
Peridex /00133002/	C	Unk	Not Reported
Maxipime	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146123	EXPEDITED (15-DAY)		LT, OT	US-SA-2020SA208980			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Cytokine Storm; Disseminated Intravascular Coagulation; Haemoglobin Decreased; Hyperglycaemia; Hyperkalaemia; Hypotension; Iron Deficiency; Lactic Acidosis; Liver Injury; Retroperitoneal	Lovenox			S	Subcutaneous	80 Mg		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Fentanyl			C	Unknown	Unk		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Midazolam			C	Unknown	Unk		Not Reported

Haematoma; Septic Shock; Shock Haemorrhagic; Swelling	Levetiracetam	C	Unknown	Unk		Not Reported
	Pantoprazole	C	Unknown	Unk		Not Reported
	Propofol	C	Unknown	Unk		Not Reported
	Otezla	C	Unknown	Unk		Not Reported
	Tocilizumab	C	Unknown	Unk		Not Reported
	Vancomycin	C	Unknown	Unk		Not Reported
	Furosemide	C	Unknown	Unk		Not Reported
	Ceftriaxone	C	Unknown	Unk		Not Reported
	Ferrous Sulfate	C	Unknown	Unk		Not Reported
	Methylprednisolone	C	Unknown	Unk		Not Reported
	Polyethylene Glycol [Macrogol]	C	Unknown	Unk		Not Reported
	Cefepime	C	Unknown	Unk		Not Reported
	Ativan	C	Unknown	Unk		Not Reported
	Docusate;Senna	C	Unknown	Unk		Not Reported
	Lactulose	C	Unknown	Unk		Not Reported
	Nicotine	C	Unknown	Unk		Not Reported
	Duoneb	C	Unknown	Unk		Not Reported
	Suboxone	C	Unknown	Unk		Not Reported
	Chlorhexidine	C	Unknown	Unk		Not Reported
	Azithromycin	C	Unknown	Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported
	Dextromethorphan	C	Unknown	Unk		Not Reported
	Meropenem	C	Unknown			Not Reported
	Sodium Polystyrene Sulfonate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146245	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489990		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin	C				Not Reported
	Clonazepam	C				Not Reported
	Estradiol	C				Not Reported
	Levothyroxin	C				Not Reported
	Latuda	C				Not Reported
	Metoprolol Succinate	C				Not Reported
	Trazodone	C				Not Reported
	Maxzide	C				Not Reported
	Trintellix	C				Not Reported
	Azithromycin	C				Not Reported
	Benzonatate	C				Not Reported
	Ceftriaxone	C				Not Reported
	Dexamethasone	C				Not Reported
	Enoxaparin	C				Not Reported
	Culturelle	C				Not Reported
	Losartan	C				Not Reported
	Vitamin C [Ascorbic Acid]	C				Not Reported
	Zinc Sulfate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146272	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489981		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Dexamethasone			C				Not Reported
	Oxygen			C				Not Reported
	Morphine			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18146998	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0489892		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Albuterol Hfa	C	Respiratory (inhalation)	2 Puff Q4h And Q6h Prn	Not Reported
	Amiodarone	C		Unk	Not Reported
	Apixaban	C	Oral	5 Mg, Bid	Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	1 G, Q8h	Not Reported
	Precedex	C		Unk	Not Reported
	Cardizem Cd	C	Oral	120 Mg, Qd	Not Reported
	Diltiazem	C		Unk	Not Reported
	Famotidine	C	Intravenous (not otherwise specified)	20 Mg Q12h	Not Reported
	Fentanyl	C		Unk	Not Reported
	Folic Acid	C	Oral	1 Mg, Qd	Not Reported
	Gabapentin	C	Oral	300 Mg, Tid	Not Reported
	Heparin	C		Unk	Not Reported
	Lantus	C	Subcutaneous	Unk Unk, Qhs	Not Reported
	Insulin Lispro	C		Sliding Scale, Qid	Not Reported
	Meropenem	C		Unk	Not Reported
	Methimazole	C		Unk	Not Reported
	Methylprednisolone	C		60 Mg, Q6h	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Propofol	C		Unk	Not Reported
	Acetaminophen	C	Oral	650 Mg, Q6h Prn 1-3	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18148781	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490161		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18148891	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490144		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome	Remdesivir			S	Unknown	Unk		Gilead
	Ceftriaxone			C		Unk		Not Reported
	Norco			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149446	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Lyophilized Remdesivir For Injection	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Dexamethasone 6 Mg Daily			C				Not Reported
	Enoxaparin 40 Mg Q12h			C				Not Reported
	Vitamin C 500 Mg Bid			C				Not Reported
	Zinc Sulfate 220 Mg Daily			C				Not Reported
	Pseudoephedrine 60 Mg Q4h Prn			C				Not Reported
	Guaifenesin/Codeine 10 Ml Q4h Prn			C				Not Reported
	Mucinex 600 Mg Bid			C				Not Reported
	Lantus 10 Units Daily			C				Not Reported
	Humalog Sliding Scale			C				Not Reported

		Ventolin			C					Not Reported
		Tylenol 650 Mg Po Q4h			C					Not Reported
		Ketorolac 10 Mg			C					Not Reported
		Ketorolac 30 Mg			C					Not Reported
		Kcl 20 Meq			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149451	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Not Reported
	Benzonatate			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149457	DIRECT	Y				42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous drip			Gilead
	Benzonatate			C				Not Reported
	Dexamethasone			C				Not Reported
	Guaifenesin-Dextromethorphan			C				Not Reported
	Melatonin			C				Not Reported
	Losartan			C				Not Reported
	Enoxaparin			C				Not Reported
	Loperamide			C				Not Reported
	Ibuprofen			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149460	DIRECT					85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Infusion Related Reaction; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Furosemide			C				Not Reported
	Spironolactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149465	DIRECT	Y				24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Dexamethasone			C				Not Reported
	Divalproex			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Norco			C				Not Reported
	Lorazepam			C				Not Reported
	Protonix			C				Not Reported
	Flomax			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149498	DIRECT	Y	DE			51 YR	Male	AFG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Blood	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

Glucose Increased; Gastrointestinal Haemorrhage; Hyponatraemia; Leukocytosis; Pneumothorax; Refusal Of Treatment By Patient; Thrombocytopenia	Dexamethasone 6 Mg Iv Once Daily	C	Not Reported
	Dexamethasone 6 Mg Iv Once Daily	C	Not Reported
	Colchicine 0.6 Mg Po Bid	C	Not Reported
	Cefepime 1 Gm Iv Q6hr	C	Not Reported
	Cefepime 1 Gm Iv Q6hr	C	Not Reported
	Azithromycin 500 Mg Iv Once Daily	C	Not Reported
	Enoxaparin 80 Mg Sq Q12hr	C	Not Reported
	Enoxaparin 80 Mg Sq Once Daily	C	Not Reported
	Enoxaparin 40 Mg Sq Q12hr	C	Not Reported
	Micafungin 100 Mg Iv Once Daily	C	Not Reported
	Pantoprazole Drip	C	Not Reported
	Pantoprazole 40 Mg Iv Q12hrs	C	Not Reported
	Tpn Custom	C	Not Reported
	Zinc Sulfate 220 Mg Po Once Daily	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149503	DIRECT		OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149507	DIRECT					68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Decreased; Depressed Level Of Consciousness; Heart Rate Decreased; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149519	DIRECT					64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2020	18149523	DIRECT					33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hyperhidrosis	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18069578	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0485585		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Death; Multiple Organ Dysfunction Syndrome; Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported
	Vitamin C Asc Acid			C				Not Reported
	Zinc			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Ketamine			C				Not Reported
	Norepinephrine			C				Not Reported

		Pantoprazole			C						Not Reported
		Propofol			C						Not Reported
		Rosuvastatin			C						Not Reported
		Cholecalciferol			C						Not Reported
		Aspirin [Acetylsalicylic Acid]			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18077392	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485708		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Tocilizumab			C				Not Reported
	Cholecalciferol			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Zinc			C				Not Reported
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cefepime			C				Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Budesonide			C				Not Reported
	Carvedilol			C				Not Reported
	Enoxaparin			C				Not Reported
	Finasteride			C				Not Reported
	Furosemide			C				Not Reported
	Kayexalate			C				Not Reported
	Insulin Regular [Insulin Bovine]			C				Not Reported
	Quetiapine			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Dextrose			C				Not Reported
	Glucagon			C				Not Reported
	Plasmalyte A			C				Not Reported
	Phenylephrine			C				Not Reported
	Sodium Chloride			C				Not Reported
	Vasopressin			C				Not Reported
	Meropenem			C				Not Reported
	Epoprostenol			C				Not Reported
	Cisatracurium			C				Not Reported
	Insulin Lispro			C				Not Reported

		Norepinephrine			C					Not Reported
		Fentanyl			C					Not Reported
		Albuterol [Salbutamol]			C					Not Reported
		Morphine			C					Not Reported
		Lisinopril			C					Not Reported
		Plasma			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149967	DIRECT	Y	OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip			Gilead
	Normal Saline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149972	DIRECT	Y	OT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;	30 MIN	Gilead
	Aripiprazole			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydrocodone/Acetaminophen			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18149982	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150714	DIRECT	Y	DE			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Pressure Decreased; Bradycardia; Cardiac Arrest; Disease Progression; Hypoxia	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150831	DIRECT	Y	DE			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Endotracheal Intubation; Therapy Cessation	Remdesivir			S				Not Reported
	Dexamethadone			C				Not Reported
	Albuterol			C				Not Reported
	Lovenox			C				Not Reported
	Tocilizumab			C				Not Reported
	Losartan			C				Not Reported
	Bumex			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18150842	DIRECT	Y				47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18151163	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

	Thiamine			C						Not Reported
	Ascorbic Acid			C						Not Reported
	Allopurinol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18151168	DIRECT	Y				78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18151171	DIRECT	Y	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18151176	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18151179	DIRECT	Y	DS, HO, LT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Artery Occlusion	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18151183	DIRECT	Y	DE			77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18151297	DIRECT	Y				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Allopurinol 100 Mg Twice Daily			C				Not Reported
	Dexamethasone 6 Mg Daily			C				Not Reported
	Enoxaparin 50mg Twice Daily			C				Not Reported
	Levothyroxine 100 Mcg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18152443	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-TEVA-2020-US-1814098		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Cardiac Arrest; Electrocardiogram Qrs Complex Prolonged; Hepatic Enzyme Increased; Hypotension; Liver Disorder; Pulseless Electrical Activity; Renal Tubular Necrosis; Respiratory Disorder	Amiodarone Hcl			S	Intravenous (not otherwise specified)	Frequency: Q1 Minute		Teva
	Amiodarone Hcl			S	Intravenous (not otherwise specified)	Frequency: Q1 Minute		Teva
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported
	Ivermectin			C				Not Reported
	Tocilizumab			C				Not Reported
	Plasma			C	Unknown			Not Reported
	Calcium Gluconate			C	Unknown			Not Reported

	Ceftriaxone	C			Not Reported
	Clinimix E	C			Not Reported
	Norepinephrine	C			Not Reported
	Phenylephrine	C			Not Reported
	Propofol	C	Unknown		Not Reported
	Sodium Bicarbonate	C			Not Reported
	Vasopressin	C			Not Reported
	Acetaminophen	C			Not Reported
	Albuterol Hfa	C			Not Reported
	Ascorbic	C			Not Reported
	Chlorhexidine	C			Not Reported
	Enoxaparin	C			Not Reported
	Epinephrine	C			Not Reported
	Etomidate	C			Not Reported
	Cholecalciferol	C			Not Reported
	Famotidine	C			Not Reported
	Heparin	C			Not Reported
	Solu-Medrol	C			Not Reported
	Metoprolol	C			Not Reported
	Petrolatum/Mineral Oil	C			Not Reported
	Ondansetron	C			Not Reported
	Rocuronium	C			Not Reported
	Kayexalate	C			Not Reported
	Zinc Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18152892	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490166		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported

	Guaifenesin	C	Unk	Not Reported
	Ipratropium	C	Unk	Not Reported
	Docusate Sodium	C	Unk	Not Reported
	Temazepam	C	Unk	Not Reported
	Senna [Senna Alexandrina Leaf]	C	Unk	Not Reported
	Aluminum Magnesium Hydroxide	C	Unk	Not Reported
	Lidocaine Viscous	C	Unk	Not Reported
	Simethicone	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18155257	DIRECT	Y	OT			84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Aspirin 81mg Daily			C				Not Reported
	Atorvastatin 80mg Daily			C				Not Reported
	Ceftriaxone 1g Daily			C				Not Reported
	Enoxarin 30mg Daily			C				Not Reported
	Insulin Aspart Sliding Sclae			C				Not Reported
	Moxifloxacin 400mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18155262	DIRECT	Y	DE, DS, HO			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18155270	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia	Remdesivir			S	Intravenous drip		3 DAY	Gilead
	Humira			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18155274	DIRECT	Y				55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Prednisone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Acetaminophen 650 Mg Po Prn Q4h			C				Not Reported
	Cholecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18155305	DIRECT	Y				35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Interaction; Therapy Cessation; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorpheniramine			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone Iv			C				Not Reported

		Doxycycline			C					Not Reported
		Enoxaparin			C					Not Reported
		Prednisone			C					Not Reported
		Zinc Sulfate			C					Not Reported
		Ondansetron Iv Prn			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18155346	DIRECT	Y	RI			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Oxygen Saturation Decreased; Posturing; Seizure	Remdesivir			S	Intravenous drip			Gilead
	Remdisevir 100mg			C				Not Reported
	Remdesivir 200mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18155353	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2020	18156396	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2020	18155282	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine	Remdesivir (Eua) 100 Mg Recon			S	Intravenous (not			Gilead

Increased; Dialysis; Therapy Cessation	Soln		otherwise specified)	
	Albumin Human 25 % Iv Premix 12.5 G	C		Not Reported
	Albuterol 90 Mcg/Actuation Hfa Mdi 4 Puff (Proair/Proventil/Ventolin)	C		Not Reported
	Azithromycin Add Vial 500 Mg	C		Not Reported
	Cefepime Add Vial 1 G (Maxipime)	C		Not Reported
	Chlorhexidine Gluconate Oral Soln 5 Ml (Peridex/Periogard)	C		Not Reported
	Dexamethasone Sodium Phosphate Inj 6 Mg (Decadron)	C		Not Reported
	Famotidine (Pf) Inj 20 Mg (Pepcid	C		Not Reported
	Fentanyl (Pf) In Ns 10 Mcg/Ml Iv Soln	C		Not Reported
	Heparin (Porcine) In 0.45% Nacl 25,000 Unit/250 Ml Iv Premix	C		Not Reported
	Mupirocin 2 % Ointment (Centany)	C		Not Reported
	Nephro-Vite / Full Spectrum 0.8 Mg 1 Tablet (Vitamin B Complex-Vit C-F	C		Not Reported
	Norepinephrine 16 Mg In Sodium Chloride 0.9% 250 Ml Iv Soln	C		Not Reported
	Propofol 1000 Mg/100 Ml Iv Soln (Diprivan)	C		Not Reported
	Ceftriaxone Inj 2 G (Rocephin)	C		Not Reported
	Furosemide Inj 40 Mg (Lasix)	C		Not Reported
	Pneumococcal 23-Val Ps Vaccine Inj 0.5 Ml (Pneumovax-23)	C		Not Reported
	Rocuronium Inj 50 Mg	C		Not Reported
	Benzonatate Cap 100 Mg (Tessalon Perles)	C		Not Reported
	Ceftazidime Add Vial 2 G (Fortaz/Tazicef)	C		Not Reported
	Enoxaparin Inj Syg 40 Mg (Lovenox)	C		Not Reported
	Vancomycin Add Vial 1.5 G	C		Not Reported

(Vancocin)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2020	18155311	DIRECT	Y	HO			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Creatinine Increased; Drug Ineffective; Therapy Cessation	Remdesivir			S				Not Reported
	Amiodarone			C				Not Reported
	Atorvastatin			C				Not Reported
	Clopidogrel			C				Not Reported
	Cholecalciferol			C				Not Reported
	Norephinephrine			C				Not Reported
	Dexamethasone			C				Not Reported
	Dutasteride			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Lactulose			C				Not Reported
	Tamsulosin			C				Not Reported
	Thiamine			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2020	18155318	DIRECT	Y	HO			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Losartan			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2020	18156438	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2020	18157489	DIRECT	Y	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir Lyophilized Ivpb 200mg			S				Not Reported
	Remdesivir Lyophilized Ivpb 200mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2020	18157516	DIRECT	Y	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Burning Sensation; Dyspnoea; Formication; Infusion Related Reaction	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	17892304	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469828		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Renal Impairment	Remdesivir			S	Unknown	Unk		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Robitussin [Guaifenesin]			C				Not Reported

	Heparin			C					Not Reported
	Insulin Aspart			C					Not Reported
	Toprol Xl			C					Not Reported
	Midazolam			C					Not Reported
	Norepinephrine			C					Not Reported
	Ondansetron			C					Not Reported
	Propofol			C					Not Reported
	Normal Saline			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18061839	EXPEDITED (15-DAY)		OT	ES-ASTELLAS-2020US023406		22 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Nausea; Vomiting	Amphotericin B, Liposome			S	Unknown	Unk Unk, Unknown Freq.		Astellas
	Remdesivir			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Linezolid			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Meropenem			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18131589	EXPEDITED (15-DAY)		DE, DS, LT	US-ROCHE-2654392		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Quadriplegia; Shock Haemorrhagic	Tocilizumab			S	Intravenous (not otherwise specified)	Most Recent Dose Of Tocilizumab Prior To Adverse Event Onset 27/Jul/2020 At 20:31		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Most Recent Dose Of Remdesivir Prior To Adverse Event Onset 29/Jul/2020 At 15:14 250 Ml		Not Reported
	Acetaminophen			C				Not Reported
	Atorvastatin			C				Not Reported
	Atropine Sulfate			C				Not Reported
	Azithromycin			C				Not Reported

Desmopressin Acetate	C	Dose 20, Unit Other	Not Reported
Dexamethasone	C		Not Reported
Doxycycline	C		Not Reported
Etomidate	C		Not Reported
Famotidine	C		Not Reported
Fentanyl Citrate	C	Dose 100, Unit Other	Not Reported
Heparin	C	Dose 1000, Unit Other	Not Reported
Insulin Glargine	C	10 U	Not Reported
Insulin Lispro	C	16 U	Not Reported
Labetalol	C		Not Reported
Lorazepam	C		Not Reported
Mannitol	C	Dose 50, Unit Other	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156630	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156638	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156639	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156640	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156644	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156647	DIRECT	Y	HO			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Mirtazapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156666	DIRECT	Y	OT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Erythema	Remdesivir	Y		S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156671	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir			S				Not Reported

Increased; Blood Creatinine Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156676	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Benzonatate			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156681	DIRECT	Y	DE			94 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cardio-Respiratory Arrest; Constipation; Hypoxia; Infrequent Bowel Movements	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156684	DIRECT	Y	DE			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Covid-19 Pneumonia; Respiratory Failure	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156699	DIRECT	Y	OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Furosemide			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Morphine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18156966	DIRECT	Y	DE, DS, HO, LT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cerebral Infarction; Covid-19 Pneumonia; Oxygen Saturation Decreased; Respiratory Failure; Shock	Remdesivir Iv			S	Intravenous bolus			Not Reported
	Remdesivir Iv			S	Intravenous bolus			Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18157127	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18157140	DIRECT	Y	DE			93 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

	Cefpodoxime	C	Not Reported
	Azithromycin	C	Not Reported
	Dexamethasone	C	Not Reported
	Metoclopramide	C	Not Reported
	Lopressor	C	Not Reported
	Keppra	C	Not Reported
	Amlodipine	C	Not Reported
	Flagyl	C	Not Reported
	Tylenol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18160845	DIRECT	Y				75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Eua			S	Intravenous (not otherwise specified)	Other Frequency:X1 Load Dose;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2020	18162862	DIRECT		DE			84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Condition Aggravated; General Physical Health Deterioration; Sudden Death	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18067776	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0485221		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not	100 Mg, Qd		Gilead

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18161750	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18161756	DIRECT						Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18161795	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18161833	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18161839	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162041	DIRECT	Y	HO			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia; Haemolytic Anaemia; Liver Disorder; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Hydroxychloroquine			S	Oral			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162504	DIRECT	Y	OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dextromethorphan-Guaifenesin			C				Not Reported
	Enoxaparin			C				Not Reported
	Methylprednisone			C				Not Reported
	Tiotropium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162511	DIRECT	Y	HO			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162767	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Haemodialysis; Hyperkalaemia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Apixaban			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Benzonatate			C				Not Reported
	Brimonidine Ophthlamic Solution			C				Not Reported
	Calcium Acetate			C				Not Reported
	Carvedilol			C				Not Reported
	Cholecalciferol			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Dorzolamide-Timolol Ophthalmic Solution			C				Not Reported
	Doxycycline			C				Not Reported
	Famotidine			C				Not Reported
	Hydralazine			C				Not Reported
	Insulin			C				Not Reported
	Melatonin			C				Not Reported
	Omega-3 Polyunsaturated Fatty Acids			C				Not Reported
	Pantoprazole			C				Not Reported
	Ceftriaxone			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18162774	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir			S				Not Reported

Increased; Liver Function Test Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163033	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Ampicillin-Sulbactam			C				Not Reported
	Apixaban			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Famotidine			C				Not Reported
	Fosphenytoin			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Albumin			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163130	DIRECT	Y	DE			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163139	DIRECT	Y	DE			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercapnia	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163175	DIRECT	Y	OT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dyspnoea; Hypertension	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Insulin			C				Not Reported
	Amlodipine			C				Not Reported
	Aspirin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Dextromethorphan-Guaifenesin			C				Not Reported
	Enoxaparin			C				Not Reported
	Ezetimibe			C				Not Reported
	Fenofibrate			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Metoprolol			C				Not Reported
	Sertraline			C				Not Reported
	Valsartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163709	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490629		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea Increased; Death; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18163713	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0490628		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Urea Increased; Death; Endotracheal Intubation; General Physical Health Deterioration	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18164223	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490625		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea Increased; Death; Thrombocytosis; Unevaluable Event	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18164704	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490670		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead
	Dexamethasone			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Tocilizumab			C				Not Reported
	Losartan			C				Not Reported
	Bumex			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18164707	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490671		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported
	Colchicine			C				Not Reported
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Micafungin			C				Not Reported
	Pantoprazole			C				Not Reported
	Tpn [Amino Acids Nos; Carbohydrates Nos;Minerals Nos;Vitamins Nos]			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18164738	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490839		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18164741	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490641		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18164769	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490630		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18167380	DIRECT	Y	DE			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Diltiazem			C				Not Reported
	Enoxaparin			C				Not Reported
	Formoterol			C				Not Reported
	Ipratropium			C				Not Reported
	Methylprednisolone			C				Not Reported
	Mometasone			C				Not Reported
	Olanzapine			C				Not Reported
	Polyethylene Glycol 3350			C				Not Reported
	Simvastatin			C				Not Reported
	Haloperidol			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18167392	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Not Reported
	Furosemide			C				Not Reported
	Chlorothiazide			C				Not Reported

	Vancomycin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18167399	DIRECT	Y	DE			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous drip			Gilead
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Ipratropium			C				Not Reported
	Miconazole Topical			C				Not Reported
	Mupirocin Topical			C				Not Reported
	Nifedipine			C				Not Reported
	Nystatin Topical			C				Not Reported
	Ticagrelor			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18167408	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18167417	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error; Product Administration Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18167427	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Remdesivir	Y		S	Intravenous drip			Not Reported
	Remdesivir	Y		S	Intravenous drip			Not Reported
	Convalesent Plasma			C				Not Reported
	Atorvastatin 20 Mg Daily			C				Not Reported
	Decadron 6 Mg Daily			C				Not Reported
	Lovenox 40 Mg Sq Daily			C				Not Reported
	Mucinex 600 Mg Bid			C				Not Reported
	Hydrochlorothiazide 25 Mg Daily			C				Not Reported
	Multivitamin Daily			C				Not Reported
	Glargine 10 Units Sq Daily			C				Not Reported
	Miralax 17 Gram Daily Prn			C				Not Reported
	Zofran 4 Mg Q6hr Prn			C				Not Reported
	Tessalon Perles 100 Mg Tid Prn			C				Not Reported
	Tylenol 1000 Mg Q 6hr Prn			C				Not Reported
	Lomotil 1 Q 6hr Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18168911	EXPEDITED (15-DAY)			US-GILEAD-2020-0490664			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2020	18170020	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Fibrillation; Bradycardia; Heart Rate Decreased	Remdesivir			S						Not Reported
	Ascorbic Acid			C						Not Reported
	Azithromycin			C						Not Reported
	Ceftriaxone			C						Not Reported
	Dexamethasone			C						Not Reported
	Lantus			C						Not Reported
	Multivitamin With Minerals			C						Not Reported
	Pantoprazole			C						Not Reported
	Thiamine			C						Not Reported
	Tocilizumab			C						Not Reported
	Zinc Sulfate			C						Not Reported
	Heparin Drip			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18100023	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487474		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Covid-19; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Insulin Glargine			C		35 Iu, Bid		Not Reported
	Pantoprazole			C		40 Mg, Qd		Not Reported
	Gabapentin			C		300 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18125836	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0489142		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Acute Respiratory Failure; Cytokine Storm; Death; Glomerular Filtration Rate Decreased; Renal Failure; Thrombocytopenia	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Definity			C		Unk		Not Reported
	Vancocin			C		Unk		Not Reported
	Vancocin			C		Unk		Not Reported

Vancocin	C	Unk	Not Reported
Vancocin	C	Unk	Not Reported
Vancocin	C	Unk	Not Reported
Vancocin	C	Unk	Not Reported
Recothrom	C	Unk	Not Reported
Sublimaze [Fentanyl]	C	Unk	Not Reported
Versed	C	Unk	Not Reported
Ketalar	C	Unk	Not Reported
Anectine	C	Unk	Not Reported
Anectine	C	Unk	Not Reported
Nimbex [Cisatracurium Besilate]	C	Unk	Not Reported
Zofran [Ondansetron]	C	Unk	Not Reported
Zofran [Ondansetron]	C	Unk	Not Reported
Decadron [Dexamethasone]	C	Unk	Not Reported
Decadron [Dexamethasone]	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Phenylephrine Hcl	C	Unk	Not Reported
Diprivan	C	Unk	Not Reported
Diprivan	C	Unk	Not Reported
Diprivan	C	Unk	Not Reported
Ephedrine	C	Unk	Not Reported
Precedex	C	Unk	Not Reported
Xylocaine [Lidocaine]	C	Unk	Not Reported
Ancef [Cefazolin Sodium]	C	Unk	Not Reported
Ultane	C	Unk	Not Reported

Neosynephrine	C	Unk	Not Reported
Magnesium Sulfate	C	Unk	Not Reported
Boostrix	C	Unk	Not Reported
Phenergan [Promethazine]	C	Unk	Not Reported
Phenergan [Promethazine]	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Omnipaque	C	Unk	Not Reported
Omnipaque	C	Unk	Not Reported
Omnipaque	C	Unk	Not Reported
Dextrose In Water	C	Unk	Not Reported
Dextrose In Water	C	Unk	Not Reported
Dextrose In Water	C	Unk	Not Reported
Glutose	C	Unk	Not Reported
Dulcolax [Bisacodyl]	C	Unk	Not Reported
Tylenol	C	Unk	Not Reported
Tylenol	C	Unk	Not Reported
Lipitor [Atorvastatin]	C	Unk	Not Reported
Lipitor [Atorvastatin]	C	Unk	Not Reported
Lipitor [Atorvastatin]	C	Unk	Not Reported
Lipitor [Atorvastatin]	C	Unk	Not Reported
Zyloprim	C	Unk	Not Reported
Zyloprim	C	Unk	Not Reported
Zyloprim	C	Unk	Not Reported
Zyloprim	C	Unk	Not Reported
Albuterol [Salbutamol]	C	Unk	Not Reported
Humalog	C	Unk	Not Reported
Humalog	C	Unk	Not Reported

Glucagen [Glucagon]	C	Unk	Not Reported
Norco	C	Unk	Not Reported
Lactated Ringers	C	Unk	Not Reported
Lactated Ringers	C	Unk	Not Reported
Lactated Ringers	C	Unk	Not Reported
Lactated Ringers	C	Unk	Not Reported
Lactated Ringers	C	Unk	Not Reported
Lactated Ringers	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Lopressor	C	Unk	Not Reported
Lopressor	C	Unk	Not Reported
Lopressor	C	Unk	Not Reported
Lopressor	C	Unk	Not Reported
Lopressor	C	Unk	Not Reported
Mobic	C	Unk	Not Reported
Imdur	C	Unk	Not Reported
Lasix [Furosemide]	C	Unk	Not Reported
Lasix [Furosemide]	C	Unk	Not Reported
Lasix [Furosemide]	C	Unk	Not Reported
Lasix [Furosemide]	C	Unk	Not Reported
Lasix [Furosemide]	C	Unk	Not Reported
Lasix [Furosemide]	C	Unk	Not Reported
Flonase [Fluticasone Propionate]	C	Unk	Not Reported
Zetia	C	Unk	Not Reported
Zetia	C	Unk	Not Reported

Zetia	C	Unk	Not Reported
Zetia	C	Unk	Not Reported
Zetia	C	Unk	Not Reported
Proscar	C	Unk	Not Reported
Proscar	C	Unk	Not Reported
Proscar	C	Unk	Not Reported
Proscar	C	Unk	Not Reported
Dulera	C	Unk	Not Reported
Glycolax	C	Unk	Not Reported
Senokot	C	Unk	Not Reported
Senokot	C	Unk	Not Reported
Senokot	C	Unk	Not Reported
Senokot	C	Unk	Not Reported
Flomax [Tamsulosin Hydrochloride]	C	Unk	Not Reported
Flomax [Tamsulosin Hydrochloride]	C	Unk	Not Reported
Flomax [Tamsulosin Hydrochloride]	C	Unk	Not Reported
Flomax [Tamsulosin Hydrochloride]	C	Unk	Not Reported
Azulfidine	C	Unk	Not Reported
Azulfidine	C	Unk	Not Reported
Azulfidine	C	Unk	Not Reported
Azulfidine	C	Unk	Not Reported
Ranexa	C	Unk	Not Reported
Nitrostat	C	Unk	Not Reported
Cepacol Ab	C	Unk	Not Reported
Bactroban [Mupirocin]	C	Unk	Not Reported
Bactroban [Mupirocin]	C	Unk	Not Reported
Bactroban [Mupirocin]	C	Unk	Not Reported
Chlorhexidine	C	Unk	Not Reported

Chlorhexidine	C	Unk	Not Reported
Chlorhexidine	C	Unk	Not Reported
Aspirin 81	C	Unk	Not Reported
Aspirin 81	C	Unk	Not Reported
Aspirin 81	C	Unk	Not Reported
Aspirin 81	C	Unk	Not Reported
Protonix	C	Unk	Not Reported
Protonix [Pantoprazole Sodium Sesquihydrate]	C	Unk	Not Reported
Methotrexate	C	Unk	Not Reported
Folvite [Folic Acid]	C	Unk	Not Reported
Folvite [Folic Acid]	C	Unk	Not Reported
Folvite [Folic Acid]	C	Unk	Not Reported
Folvite [Folic Acid]	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Exparel	C	Unk	Not Reported
Peridex [Chlorhexidine Gluconate]	C	Unk	Not Reported
Peridex [Chlorhexidine Gluconate]	C	Unk	Not Reported
Lacri Lube	C	Unk	Not Reported
Lacri Lube	C	Unk	Not Reported
Lacri Lube	C	Unk	Not Reported
Bactroban Ointment	C	Unk	Not Reported
Sodium Phosphate	C	Unk	Not Reported
Sodium Phosphate	C	Unk	Not Reported
Keppra	C	Unk	Not Reported
Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported

Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported
Cathflo Activase	C	Unk	Not Reported
Diovan	C	Unk	Not Reported
Diovan	C	Unk	Not Reported
Diovan	C	Unk	Not Reported
Klor Con	C	Unk	Not Reported
Levaquin	C	Unk	Not Reported
Mucinex	C	Unk	Not Reported
Solu-Medrol	C	Unk	Not Reported
Solu-Medrol	C	Unk	Not Reported
Cleocin [Clindamycin Hydrochloride]	C	Unk	Not Reported
Amidate [Etomidate]	C	Unk	Not Reported
Duoneb	C	Unk	Not Reported
Robitussin [Guaifenesin]	C	Unk	Not Reported
Rocuronium	C	Unk	Not Reported
Levophed	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Calquence	C	Unk	Not Reported
Pepcid [Famotidine]	C	Unk	Not Reported
Neo-Synephrine	C	Unk	Not Reported
Pitressin [Vasopressin]	C	Unk	Not Reported
Flagyl [Metronidazole]	C	Unk	Not Reported
Ativan	C	Unk	Not Reported
Ativan	C	Unk	Not Reported
Norcuron	C	Unk	Not Reported
Isordil	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18146936	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0489947		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; General Physical Health Deterioration	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Bivalirudin			C	Unknown	Unk		Not Reported
	Escitalopram			C	Unknown			Not Reported
	Fentanyl			C	Unknown	Unk		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Norepinephrine			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Propofol			C	Unknown	Unk		Not Reported
	Ramipril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168932	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168941	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168950	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168956	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Paravenous Drug Administration; Peripheral Ischaemia; Peripheral Swelling	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18168971	DIRECT	Y				28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169006	DIRECT					81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Hypersensitivity Reaction	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169046	DIRECT	Y	DE			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alanine Aminotransferase Increased; General Physical Health Deterioration; Supraventricular Tachycardia	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169222	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Albuterol 90 Mcg/Inh Inhalation Aerosol			C				Not Reported
	Azithromycin 250 Mg			C				Not Reported
	Dexamethasone 6 Mg			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Ipratropium Hfa Inhaler			C				Not Reported
	Prednisone 20 Mg			C				Not Reported
	Acetaminophen 650 Mg			C				Not Reported
	Tramadol 50 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169331	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Cardio-Respiratory Arrest; Hypoxia; Pulse Absent;	Remdesivir			S	Intravenous bolus			Gilead

Respiratory Arrest;
Unresponsive To Stimuli

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169712	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Lacrimation Increased	Remdesivir			S	Intravenous (not otherwise specified)			Amerisource Bergen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18169986	DIRECT					59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18170056	DIRECT	Y	DE			94 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Blood Creatinine Increased; Oxygen Saturation Decreased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18171001	EXPEDITED (15-DAY)		DE, DS, HO, OT	US-GILEAD-2020-0490901		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead

	Tocilizumab			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18171253	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490639		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Thrombocytosis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18171270	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490895		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18171574	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490893		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C	Intravenous (not otherwise specified)	360 Mg, Once		Not Reported
	Asa			C				Not Reported
	Amlodipine			C				Not Reported
	Losartan			C				Not Reported
	Hydralazine			C				Not Reported
	Metoprolol			C				Not Reported
	Cellcept [Mycophenolate Mofetil Hydrochloride]			C				Not Reported
	Prograf			C				Not Reported
	Zosyn			C				Not Reported

	Zyvox			C					Not Reported
	Haldol [Haloperidol]			C					Not Reported
	Lovenox Hp			C					Not Reported
	Decadron A			C					Not Reported
	Amiodarone			C					Not Reported
	Tpn [Amino Acids Nos; Carbohydrates Nos;Minerals Nos;Vitamins Nos]			C					Not Reported
	Propofol			C					Not Reported
	Vecuronium [Vecuronium Bromide]			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18171712	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490902		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Apap			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Decadron A			C				Not Reported
	Famotidine			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Zinc Sulphate			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18172234	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490894		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18173772	EXPEDITED (15-DAY)		LT, OT	US-SA-2020SA215781			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Cytokine Storm; Disseminated Intravascular Coagulation; Haemoglobin Decreased; Hyperglycaemia; Hyperkalaemia; Hypotension; Iron Deficiency; Lactic Acidosis; Liver Injury; Retroperitoneal Haematoma; Septic Shock; Shock Haemorrhagic; Swelling	Lovenox			S	Subcutaneous	80 Mg		Sanofi
	Fentanyl			S	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Metoprolol Salt Not Specified			S	Unknown	Unk		Not Reported
	Midazolam			S	Unknown	Unk		Not Reported
	Levetiracetam			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Propofol			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk		Sanofi
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Ferrous Sulfate			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Macrogol			S	Unknown	Unk		Not Reported
	Cefepime Hydrochloride			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lactulose			S	Unknown	Unk		Sanofi
	Nicotine			S	Unknown	Unk		Sanofi
	Chlorhexidine Salt Not Specified			S	Unknown	Unk		Not Reported
	Dextromethorphan Hydrobromide			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown			Not Reported
	Sodium Polystyrene Sulfonate			S		Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

			Duoneb	S	Unknown	Unk			Not Reported
			Suboxone	S		Unk			Not Reported
			Acetaminophen	S	Unknown	Unk			Not Reported
			Docusate Sodium;Senna	S	Unknown	Unk			Not Reported
			Otezla	S	Unknown	Unk			Not Reported
			Remdesivir	S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18173870	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490928		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18173875	DIRECT	Y	HO			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acyclovir 850 Mg			C				Not Reported
	Ceftriaxone 2 Gm			C				Not Reported
	Enoxaparin 120 Mg Q12h			C				Not Reported
	Methylprednisolone 125mg			C				Not Reported
	Pantoprazole 40mg Daily			C				Not Reported
	Piperacillin/Tazobactam 3.375			C				Not Reported
	Dexamethasone 6 Mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18173879	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous drip		Gilead
	Ceftriaxone 2g Qd	C			Not Reported
	Azithromycin 500mg Qd	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2020	18173903	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490911		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous (not otherwise specified)	1 Dosage Form		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18027827	EXPEDITED (15-DAY)			US-GILEAD-2020-0482378			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18029374	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482872		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Aztreonam			C	Intravenous (not otherwise specified)	2 G Q8hr		Not Reported

	Clindamycin		C		Unk	Not Reported
	Dexamethasone		C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
	Lidocaine		C		Unk	Not Reported
	Enoxaparin [Enoxaparin Sodium]		C		Unk	Not Reported
	Breo Ellipta		C		Unk	Not Reported
	Lactobacillus		C		Unk	Not Reported
	Pantoprazole		C		Unk	Not Reported
	Polyethylene Glycol 3350		C		Unk	Not Reported
	Potassium Chloride		C		Unk	Not Reported
	Docusate;Sennoside A+B		C		Unk	Not Reported
	Spiriva		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18039530	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0483230		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Triglycerides Increased; Death; International Normalised Ratio Increased; Prothrombin Time Prolonged; Thrombocytopenia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Diprivan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Lovenox [Enoxaparin Sodium]			S	Subcutaneous	40 Mg		Not Reported
	Decadron [Dexamethasone]			C		6 Mg, Qd		Not Reported
	Aspirin Kent [Acetylsalicylic Acid]			C				Not Reported
	Precedex			C				Not Reported
	Ativan			C		Unk		Not Reported
	Glucerna [Nutrients Nos]			C		Unk		Not Reported
	Humulin R			C		Unk		Not Reported
	Rocephin [Ceftriaxone]			C		Unk		Not Reported

	Benadryl [Diphenhydramine Hydrochloride]	C	Unk		Not Reported
	Ns	C			Not Reported
	Morphine	C	Unk		Not Reported
	Vecuronium	C	Unk		Not Reported
	Tylenol	C	Unk		Not Reported
	Albuterol Sulfate Hfa	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18050980	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0484178		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19; Haematuria; Proteinuria; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Epinephrine			C	Intravenous (not otherwise specified)	0.09		Not Reported
	Vecuronium			C				Not Reported
	Dexamethasone			C				Not Reported
	Midazolam			C				Not Reported
	Fentanyl			C				Not Reported
	Tpn [Amino Acids Nos; Carbohydrates Nos;Minerals Nos;Vitamins Nos]			C				Not Reported
	Plasma			C				Not Reported
	Nitric Oxide			C				Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	800 Mg		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	800 Mg		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	650 Unk		Not Reported
	Albuterol [Salbutamol]			C	Intravenous (not otherwise specified)	200 Mg		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Augmentin [Amoxicillin; Clavulanate Potassium]	C			Not Reported
Oxygen	C			Not Reported
Dexmedetomidine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Dexmedetomidine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cefepime	C		Unk	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	20 Mg/Ml	Not Reported
Thrombin	C	Topical	Unk	Not Reported
Albumin Human	C	Intravenous (not otherwise specified)	12.5 G	Not Reported
Albumin Human	C	Intravenous (not otherwise specified)	12.5 Unk	Not Reported
Acetaminophen	C	Oral	650 Mg	Not Reported
Enoxaparin	C	Subcutaneous	20 Mg	Not Reported
Diphenhydramine	C	Intravenous (not otherwise specified)	12.5 Mg	Not Reported
Diphenhydramine	C	Intravenous (not otherwise specified)	12.5 Mg	Not Reported
Cisatracurium	C	Intravenous (not otherwise specified)	4.4 Mg	Not Reported
Cisatracurium	C	Intravenous (not otherwise specified)	0.4 Mg/Ml	Not Reported
Cisatracurium	C	Intravenous (not otherwise specified)	4.37 Unk	Not Reported
Bacitracin	C	Topical	Unk	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	10 Mg/Ml	Not Reported
Bisacodyl	C	Rectal	10 Mg	Not Reported
Hydrocortisone Sodium	C	Intravenous (not	13.5 Mg	Not Reported

Succinate		otherwise specified)		
Polyethylene Glycol [Macrogol]	C		17 G	Not Reported
Phenobarbital	C	Oral	120 Mg	Not Reported
Phenobarbital	C	Oral	130 Mg	Not Reported
Docusate Sodium	C	Oral	100 Mg	Not Reported
Parenteral	C	Intravenous (not otherwise specified)	22 Ml	Not Reported
Parenteral	C	Intravenous (not otherwise specified)	72.4 Ml	Not Reported
Parenteral	C	Intravenous (not otherwise specified)	77.9 Unk	Not Reported
Parenteral	C	Intravenous (not otherwise specified)	53.2 Unk	Not Reported
Intralipid [Glycine Max Seed Oil]	C	Intravenous (not otherwise specified)	500 Ml	Not Reported
Intralipid [Glycine Max Seed Oil]	C	Intravenous (not otherwise specified)	1000 Ml	Not Reported
Intralipid [Glycine Max Seed Oil]	C	Intravenous (not otherwise specified)	500 Ml	Not Reported
Magnesium Citrate	C	Oral	148 Ml	Not Reported
Levocarnitine	C	Oral	1000 Mg	Not Reported
Acetazolamide	C	Oral	250 Mg	Not Reported
Anakinra	C	Subcutaneous	100 Mg	Not Reported
Chlorothiazide	C	Intravenous (not otherwise specified)	Unk	Not Reported
Aciclovir	C	Oral	400 Mg	Not Reported
Sodium Phosphate	C	Rectal	Unk	Not Reported
Caspofungin	C	Intravenous (not otherwise specified)	70 Mg	Not Reported
Caspofungin	C	Intravenous (not otherwise specified)	50 Unk	Not Reported
Lansoprazole	C	Oral	30 Mg	Not Reported

	Meropenem			C	Intravenous (not otherwise specified)	880 Mg			Not Reported
	Zinc Sulfate			C	Oral	220 Mg			Not Reported
	Vitamin C [Ascorbic Acid]			C	Oral	500 Mg			Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	0.9 %			Not Reported
	Sodium Polystyrene Sulfonate			C	Oral	15 G			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18068864	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0485562		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vitamin C [Ascorbic Acid]			C	Oral			Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Zinc			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Levothyroxine			C				Not Reported
	Pantoprazole			C				Not Reported
	Tamsulosin			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18143285	EXPEDITED (15-DAY)		CA, HO, OT	US-GILEAD-2020-0489915			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Intraventricular Haemorrhage; Patent Ductus Arteriosus;	Remdesivir			S	Transplacental	Unk		Gilead
	Hydroxychloroquine			C	Transplacental			Not Reported
	Azithromycin			C	Transplacental			Not Reported
	Nitric Oxide			C	Transplacental			Not Reported

Premature Baby; Tuberous Sclerosis Complex	Plasma		C	Transplacental		Not Reported
	Tocilizumab		C	Transplacental		Not Reported
	Betamethasone		C	Transplacental		Not Reported
	Magnesium Sulfate		C	Transplacental		Not Reported
	Propofol		C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18174310	DIRECT	Y	DE			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Pulse Absent; Ventricular Fibrillation	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175245	DIRECT	Y	DS, HO, LT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Bradycardia; Bundle Branch Block Left	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported
	Dopamine			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lisinopril			C				Not Reported
	Metformin			C				Not Reported
	Mupirocin Ointment			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175251	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported

		Dexamethasone			C					Not Reported
		Azithromycin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18175257	DIRECT	Y	HO			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Swelling	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18179414	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir Lyophilized Powder			S	Intravenous (not otherwise specified)			Gilead
	Actemra			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18179422	DIRECT	Y	HO			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Ejection Fraction Decreased; Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18179430	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Hypoxia; Supraventricular Tachycardia; Troponin I Increased	Remdesivir			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18179438	DIRECT	Y	DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure; Unresponsive To Stimuli	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18179466	DIRECT	Y	OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extravasation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18179471	DIRECT	Y	HO			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S			3 DAY	Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18179487	DIRECT	Y	HO			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead
	Acetaminophen			C				Not Reported
	Albuterol Sulfate			C				Not Reported
	Asorbic Acid			C				Not Reported

	Clonidipine 0.1mg Patch	C	Not Reported
	Dexamethasone	C	Not Reported
	Docusate	C	Not Reported
	Enoxaparin	C	Not Reported
	Ativan	C	Not Reported
	Zosyn	C	Not Reported
	Thiamine	C	Not Reported
	Zinc Sulfate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18180301	DIRECT	Y	OT			25 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2020	18180515	DIRECT	Y	HO, OT			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Exposure During Pregnancy; Haemangioma Of Liver; Hepatic Lesion; Liver Function Test Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	17975539	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477764		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Maternal Exposure During Pregnancy	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18040153	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0483271		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Bradycardia; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Levophed			C		Unk		Not Reported
	Precedex			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Dexamethasone			C	Oral	6 Mg, Qd		Not Reported
	Morphine Sulfate			C	Intravenous (not otherwise specified)	4 Mg		Not Reported
	Lorazepam			C	Intravenous (not otherwise specified)	2 Mg		Not Reported
	Tums [Calcium Carbonate]			C	Oral	550 Mg, Tid		Not Reported
	Insulin Regular Hm			C	Subcutaneous	Unk		Not Reported
	Insulin Nph [Insulin Isophane Bovine]			C	Subcutaneous	Unk		Not Reported
	Camphor			C	Topical	1 Dosage Form, Prn		Not Reported
	Dextrose In Water			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Glucagon			C	Intramuscular	1 Mg		Not Reported
	Heparin			C	Subcutaneous	5,000 Units		Not Reported
	Insulin Lispro			C	Subcutaneous	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	125 Mg, Once		Not Reported

Albuterol;Ipratropium	C	Respiratory (inhalation)	1 Dosage Form, Q4hr	Not Reported
Acetaminophen	C	Other	500 Mg, Q6h	Not Reported
Acetaminophen	C	Intravenous (not otherwise specified)	1000 Mg, Once	Not Reported
Aspirin [Acetylsalicylic Acid]	C		81 Mg, Qd	Not Reported
Fluoxetine	C	Other	20 Mg, Qd	Not Reported
Mupirocin	C	Nasal	10 Doses	Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported
Enoxaparin	C	Subcutaneous	40 Mg, Qd	Not Reported
Promethazine	C	Topical	25 Mg, Q6h	Not Reported
Potassium Chloride	C	Intravenous (not otherwise specified)	250 Ml, Once	Not Reported
Potassium Phosphates	C		250 Ml, Once	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	20 Mg, Once	Not Reported
Definity	C	Intravenous (not otherwise specified)	Unk	Not Reported
Atorvastatin	C	Other	80 Mg, Qd	Not Reported
Hydralazine	C	Intravenous (not otherwise specified)	10 Mg, Q6h	Not Reported
Amlodipine	C	Other	5 Mg, Qd	Not Reported
Insulin Glargine	C	Subcutaneous	8 Units	Not Reported
Midazolam	C	Intravenous (not otherwise specified)	40 Mg, Once	Not Reported
Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	Unk	Not Reported
Albumin (Human)	C	Intravenous (not otherwise specified)	Unk	Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported

	Ceftriaxone	C	Intravenous (not otherwise specified)	Unk Unk, Qd		Not Reported
	Bisacodyl	C	Oral	10 Mg, Once		Not Reported
	Labetalol	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Metolazone	C	Oral	5 Mg, Once		Not Reported
	Phenylephrine	C		Unk		Not Reported
	Vasopressin	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Folic Acid	C		1 Mg, Qd		Not Reported
	Thiamine	C		Unk		Not Reported
	Cefazolin	C		2 G, Bid		Not Reported
	Renvela	C		Unk		Not Reported
	Miralax	C	Other	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18044522	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484016		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Renal Failure; Respiratory Failure; Septic Shock	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Cefepime			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Methylprednisolone			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Pantoprazole			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18077843	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485590		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin			S	Oral	40 Mg, Qd		Not Reported
	Atorvastatin			S				Not Reported
	Acetaminophen			C		Unk		Not Reported
	Metformin			C				Not Reported
	Sitagliptin			C				Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Chlorhexidine			C		Unk		Not Reported
	Docusate			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Insulin Detemir			C		Unk		Not Reported
	Insulin Regular [Insulin Bovine]			C		Unk		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18081722	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486573		86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Covid-19; Inflammatory Marker Increased; Oxygen Saturation Decreased; Procalcitonin Increased; Respiratory Disorder; Superinfection Bacterial; White Blood Cell Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Ascorbic Acid			C	Intravenous (not otherwise specified)	3000 Mg		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	80 Mg		Not Reported
	Thiamin [Thiamine]			C	Oral	200 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	60 Mg		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	40 Mg		Not Reported

	Atorvastatin	C	Oral	80 Mg	Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Oral	81 Mg	Not Reported
	Melatonin	C	Oral	6 Mg	Not Reported
	Fluticasone	C	Respiratory (inhalation)	100 Mcg	Not Reported
	Budesonide	C	Respiratory (inhalation)	0.5 Mg	Not Reported
	Vitamin D [Colecalciferol]	C		Unk	Not Reported
	Zinc Sulfate	C	Oral	220 Mg	Not Reported
	Methimazole	C	Oral	5 Mg	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G	Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	1 G	Not Reported
	Acetylcysteine	C	Oral	600 Mg	Not Reported
	Omnipaque	C		100 Ml	Not Reported
	Plasma	C			Not Reported
	Oxygen	C			Not Reported
	Stromectol	C	Oral	16.5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18116161	EXPEDITED (15-DAY)		HO, LT	BR-ROCHE-2652876		68 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tracheobronchitis	Tocilizumab			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose Of Tocilizumab Prior To Adverse Event Onset 25/Jul/2020 At 11:04		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Most Recent Dose Of Remdesivir Prior To Adverse Event Onset		Not Reported

						26/Jul/2020 At 15:00 100 Ml Most Recent			
	Ceftriaxone			C					Not Reported
	Enoxaparin			C					Not Reported
	Enoxaparin			C					Not Reported
	Azithromycin			C					Not Reported
	Dexamethasone			C					Not Reported
	Dipyrone			C					Not Reported
	Pantoprazole			C					Not Reported
	Plasil			C					Not Reported
	Sinvastatina			C					Not Reported
	Puran T4			C					Not Reported
	Precedex			C					Not Reported
	Amiodarone			C		8 Capsule Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18116916	EXPEDITED (15-DAY)		DS, LT	US-GILEAD-2020-0486170		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Rocephine			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Potassium Phosphates			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Protonix [Omeprazole]			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18178375	EXPEDITED (15-DAY)		OT	ES-ROCHE-2663092		37 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypertransaminasaemia	Roactemra	S	Intravenous (not otherwise specified)	Not Reported
	Remdesivir	S	Intravenous (not otherwise specified)	Not Reported
	Remdesivir	S	Intravenous (not otherwise specified)	Not Reported
	Paracetamol	C	Respiratory (inhalation)	Not Reported
	Eplerenona	C	Oral	Not Reported
	Colchicina	C	Oral	Not Reported
	Dexametasona	C	Intravenous (not otherwise specified)	Not Reported
	Dexametasona	C	Oral	Not Reported
	Combiprasal	C	Respiratory (inhalation)	Not Reported
	Clexane	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180221	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180225	DIRECT	N					Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180438	DIRECT	Y				26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir				S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180739	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous bolus			Gilead
	Amlodipine 5mg			C				Not Reported
	Ascorbic Acid 500mg			C				Not Reported
	Azithromycin 500mg			C				Not Reported
	Ceftriaxone 2g			C				Not Reported
	Cholecalciferol 25 Mcg			C				Not Reported
	Dexamethasone			C				Not Reported
	Dextromethorphan Guaifenesin			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Famotidine			C				Not Reported
	Lantus			C				Not Reported
	Humalog			C				Not Reported
	Melatonin			C				Not Reported
	Kayexalate			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180883	DIRECT	N	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Kepra			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Decadron			C				Not Reported
	Heparin			C				Not Reported
	Lasix			C				Not Reported
	Lopressor			C				Not Reported
	Humulin R Insulin			C				Not Reported

		Acetaminophen			C				Not Reported
		Hydromet			C				Not Reported
		Decadron			C				Not Reported
		Zosyn			C				Not Reported
		Flomax			C				Not Reported
		Lopressor			C				Not Reported
		Colace			C				Not Reported
		Lactated Ringers			C				Not Reported
		Klor-Con			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180888	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Tylenol			C				Not Reported
	Acetylcysteine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Coreg			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Diltiazem			C				Not Reported
	Dornase Alpha Nebs			C				Not Reported
	Doxycyline			C				Not Reported
	Famotidine			C				Not Reported
	Vancomycin			C				Not Reported
	Warfarin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180899	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asphyxia; Completed Suicide; Pain; Pulse Absent	Remdesivir	Y		S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180938	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous bolus			Gilead
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Lantus			C				Not Reported
	Humalog			C				Not Reported
	Ivermectin			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18180941	DIRECT	Y	DE			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous bolus			Gilead
	Albuterol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Simethicone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Lorazepam			C				Not Reported

	Melatonin			C						Not Reported
	Ondandsetron			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18182373	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0491289		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18183216	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0491408		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18185264	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous drip			Gilead
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Calcitriol			C				Not Reported
	Cefepime			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxazosin			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Finasteride			C				Not Reported
	Hydralazine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Simvastatin			C				Not Reported

	Vancomycin			C						Not Reported
	Zinc Sulfate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18185271	DIRECT	Y	OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18186567	DIRECT	Y	OT			23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir 200mg Load, 100 Mg Dilay			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2020	18187080	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Computer Issue; Product Dose Omission In Error	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2020	18185278	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2020	18185286	DIRECT					59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Throat Tightness	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C				Not Reported
	Ketorolac			C				Not Reported
	Symbicort			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Atorvastatin			C				Not Reported
	Aspirin			C				Not Reported
	Tessalon			C				Not Reported
	Phenergan With Codeine			C				Not Reported
	Delsym			C				Not Reported
	Losartan			C				Not Reported
	Diphenhydramine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18185344	DIRECT	Y	OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hyperhidrosis; Nausea	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg X1, 100mg X1;		Gilead
	Dexadron			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Acetominophen			C				Not Reported
	Melatonin			C				Not Reported
	Zinc			C				Not Reported
	Robotussin Dm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18185353	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Furosemide			C				Not Reported
	Norepinephrine Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18185359	DIRECT	Y	DS			55 YR	Male	AFG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Replacement Therapy	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2020	18186994	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Treatment Dates: 24-Aug-2020-24-Aug-2020		Gilead
	Albuterol Inhaler			C				Not Reported
	Amlodipine			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Symbicort			C				Not Reported
	Enoxaparin			C				Not Reported
	Losartan			C				Not Reported
	Metoprolol			C				Not Reported
	Potassium Chloride			C				Not Reported
	Requip			C				Not Reported
	Theophylline			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18045788	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0483629		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Glomerular Filtration Rate Decreased; Hypotension	Remdesivir			S	Unknown	200 Mg		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead
	Propofol			C	Intravenous (not otherwise specified)	10 Mg		Not Reported
	Propofol			C				Not Reported
	Tylenol			C	Oral	650 Mg		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Atorvastatin			C	Oral	20 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Piperacillin / Tazobactam			C	Intravenous (not otherwise specified)	3.375 G		Not Reported
	Heparin			C	Intravenous (not otherwise specified)	25000 Units		Not Reported
	Zofran [Ondansetron]			C	Intravenous (not otherwise specified)	4 Mg		Not Reported
	Calquence			C	Oral	100 Mg		Not Reported
	Lasix [Furosemide]			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Potassium Chloride			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Fentanyl			C		10 Mg		Not Reported

	Fentanyl			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18061137	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484791		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19 Pneumonia; Dyspnoea; Liver Function Test Increased; Tachycardia; Tachypnoea	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Oxygen			C				Not Reported
	Decadron [Dexamethasone]			C				Not Reported
	Precedex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18068860	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-GILEAD-2020-0484987		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Artery Occlusion; Cerebrovascular Accident	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	180 Mcg		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg, Bid		Not Reported
	Insulin Detemir			C	Subcutaneous	28 Units		Not Reported
	Insulin Aspart			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18131057	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0489362		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Covid-19 Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18147241	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489781		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulseless Electrical Activity; Respiratory Distress; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Norepinephrine			C				Not Reported
	Epinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18185222	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05011			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Hypokinesia	Ceftriaxone			S	Transplacental	500 Milligram, Unk		Lupin
	Azithromycin			S	Transplacental	250 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Transplacental	400 Milligram, Bid (For Two Doses)		Lupin
	Hydroxychloroquine			S	Transplacental	200 Milligram, Bid (For Eight Doses)		Lupin
	Methylprednisolone			S	Transplacental	125 Milligram, (One Dose)		Lupin
	Methylprednisolone			S	Transplacental	40 Milligram, Bid		Lupin
	Methylprednisolone			S	Transplacental	20 Milligram, Qd (Tapered Over 5 Days0		Lupin
	Betamethasone			S	Transplacental	12 Milligram, Qd (Single Dose Repeated For One		Lupin

							Dose 24 Hours Later)			
		Remdesivir			S	Transplacental	200 Milligram, Qid			Not Reported
		Remdesivir			S	Transplacental	100 Milligram, Qd (Nine Doses)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18185223	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-04872		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Ceftriaxone			S	Intravenous (not otherwise specified)	500 Milligram, Unk (Course Completed)		Lupin
	Azithromycin			S	Oral	250 Milligram, Qd (Course Completed)		Lupin
	Hydroxychloroquine			S	Oral	400 Milligram, Bid (For Two Doses)		Lupin
	Hydroxychloroquine			S	Oral	200 Milligram, Bid (For Eight Doses) (Course Completed)		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	125 Milligram, (One Dose)		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	40 Milligram, Bid		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	20 Milligram, Qd (Tapered Over 5 Days0		Lupin
	Betamethasone			S	Intramuscular	12 Milligram, Qd (Single Dose Repeated For One Dose 24 Hours Later)		Lupin
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram, Qid		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd (Nine Doses) (Course Completed)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18186433	DIRECT	Y	OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S				Gilead
	Zosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18186556	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported
	Allopurinol			C				Not Reported
	Apixaban			C				Not Reported
	Labetalol			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18186714	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Apixaban 5 Mg			C				Not Reported
	Dexamethasone 6 Mg Iv Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18186720	DIRECT	Y	OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S				Not Reported

	Remdesivir			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18186792	DIRECT	Y				32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18186973	DIRECT	Y	OT			49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18186979	DIRECT		LT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Artery Thrombosis	Remdesivir	Y		S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18186988	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18187076	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18187247	DIRECT	Y	DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Bacterial; Pulmonary Embolism	Remdesivir			S				Not Reported
	Dexamethasone 20 Mg Iv Daily			C				Not Reported
	Enoxaparin 80 Mg Iv Bid			C				Not Reported
	Guaifenesin 600 Mg Er Bid			C				Not Reported
	Ipratropium Hfa Inhaler 2 Puffs Bid			C				Not Reported
	Lorazepam 2 Mg Iv Once			C				Not Reported
	Momentasone - Formoterol 2 Puffs Bid			C				Not Reported
	Morphine 2 Mg Iv X1			C				Not Reported
	Nifedipine 50 Mg Er Po Daily			C				Not Reported
	Hydromorphone Pca			C				Not Reported
	Albuterol 2 Puffs Q4h Prn			C				Not Reported
	Lorazepam 1 Mg Iv Q1h Prn			C				Not Reported
	Morphine 1 Mg Iv Q3h Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18187258	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir Solution			S				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18187305	DIRECT	Y	DE			91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased; Tachypnoea	Remdesivir			S				Gilead
	Amlodipine 5 Mg Po Daily			C				Not Reported
	Atenolol 25 Mg Po Daily			C				Not Reported
	Atorvastatin 20 Mg Po Daily			C				Not Reported
	Dexamethasone 6 Mg Iv Daily			C				Not Reported
	Enoxaparin 30 Mg Subq Daily			C				Not Reported
	Mvi 1 Tab Po Daily			C				Not Reported
	Pantoprazole 40 Mg Dr Po Daily			C				Not Reported
	Hydromorphone Pca			C				Not Reported
	Bisacodyl 10 Mg Per Rectum Prn			C				Not Reported
	Lorazepam1 Mg Iv Q1h Prn			C				Not Reported
	Morphine 2 Mg Iv Q4h Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18188206	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0491662		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Hypercapnia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18188298	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0491446		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alanine Aminotransferase Increased; Death; Supraventricular Tachycardia; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S				Gilead
	Ceftriaxone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18188424	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0491661		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Unknown	Unk		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol Sulfate			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Clonidine			C		0.1mg Patch		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Docusate			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Zosyn			C		Unk		Not Reported
	Thiamine			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18189075	EXPEDITED (15-DAY)		DE, LT, OT	US-SA-2020SA222861			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Triglycerides Increased; Death; International Normalised Ratio Increased; Off Label Use; Prothrombin Time Prolonged; Thrombocytopenia	Lovenox			S	Subcutaneous	40 Mg		Sanofi
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Not Reported
	Decadron [Dexamethasone]			C		Unk		Not Reported
	Aspirin Kent [Acetylsalicylic Acid]			C		Unk		Not Reported

Precedex	C	Unk	Not Reported
Ativan	C	Unk	Not Reported
Glucerna [Nutrients Nos]	C	Unk	Not Reported
Humulin R	C	Unk	Not Reported
Rocephin [Ceftriaxone]	C	Unk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unk	Not Reported
Ns	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Vecuronium	C	Unk	Not Reported
Tylenol	C	Unk	Not Reported
Albuterol Sulfate Hfa	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18189947	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0491622		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Bacterial Colitis; Cardio-Respiratory Arrest; Cardiogenic Shock; Endotracheal Intubation Complication; Multiple Organ Dysfunction Syndrome; Septic Shock; Ventricular Fibrillation; Withdrawal Of Life Support	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18190972	DIRECT		DE			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Complication Associated	Remdesivir			S				Not Reported

With Device; Encephalitis; General Physical Health Deterioration; Haemodialysis; Hypoxia; Intestinal Perforation; Mental Disorder; Pneumonia Klebsiella; Pneumonia Streptococcal; Pneumoperitoneum; Pneumothorax; Renal Impairment; Respiratory Depression; Urinary Tract Candidiasis	N/A			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18190990	DIRECT		DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Bradycardia; Condition Aggravated; Oxygen Saturation Decreased	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191150	DIRECT	Y				40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191162	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir			S				Not Reported

Increased; Aspartate Aminotransferase Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191181	DIRECT	Y	OT			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Morphine Sulfate			C				Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Albuterol			C				Not Reported
	Budesonide			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191191	DIRECT	Y	OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191198	DIRECT	Y				39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191207	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Hydroxyzine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191264	DIRECT	Y				37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin-Codeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191283	DIRECT	Y				39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191292	DIRECT	Y	RI			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18191299	DIRECT	Y	RI			27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18192292	DIRECT	Y	DE, OT			90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2020	18192351	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; International Normalised Ratio Increased; Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	17969652	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0477741		87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Bradycardia; Cardiac Arrest; Death; Hypoxia; Pyrexia; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18045226	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0483668		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Bilirubin Increased; Covid-19; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin			S	Oral	10 Mg		Not Reported
	Enoxaparin			S	Subcutaneous	80 Mg		Not Reported
	Piperacillin And Tazobactam			S	Intravenous (not otherwise specified)	3.375 G		Not Reported
	Aspirin (E.C.)			C	Oral	162 Mg		Not Reported
	Doxycycline			C	Oral	100 Mg		Not Reported
	Hydrocortisone			C	Intravenous (not otherwise specified)	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18077663	EXPEDITED (15-DAY)		OT	SK-BAUSCH-BL-2020-021078		38 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Dexamethasone		S	Oral	Valeant
	Metamizol (Metamizole)		S	Oral	Not Reported
	Moxifloxacin		S	Oral	Not Reported
	Remdesivir		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18089522	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486614		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
	Trazodone			C	Oral	25 Mg		Not Reported
	Dexamethasone			C	Oral	6 Mg		Not Reported
	Acetaminophen			C	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Potassium			C	Oral	40 Meq		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18107532	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487812		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa			C				Not Reported
	Apixaban			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Insulin			C				Not Reported
	Ascorbic			C				Not Reported
	Protonix			C				Not Reported
	Oxygen			C				Not Reported

	Atorvastatin			C						Not Reported
	Mirapex			C						Not Reported
	Budesonide			C						Not Reported
	Eliquis			C						Not Reported
	Cholecalciferol			C						Not Reported
	Fentanyl			C						Not Reported
	Sodium Zirconium Cyclosilicate			C						Not Reported
	Aspirin [Acetylsalicylic Acid]			C						Not Reported
	Pramipexole			C						Not Reported
	Enoxaparin			C						Not Reported
	Ondansetron			C						Not Reported
	Dexamethasone			C						Not Reported
	Acetaminophen			C						Not Reported
	Naloxone			C						Not Reported
	Propofol			C						Not Reported
	Levofloxacin			C						Not Reported
	Levothyroxine			C						Not Reported
	Memantine			C						Not Reported
	Metoprolol			C						Not Reported
	Pantoprazole			C						Not Reported
	Zinc			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18125846	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0488967		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Ivermectin			C		Unk		Not Reported
	Dexamethasone			C				Not Reported
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Benzonatate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18135543	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489429		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; International Normalised Ratio Increased; Liver Function Test Increased; Vitamin K Deficiency	Remdesivir	S	Intravenous drip	200 Mg	Gilead
	Remdesivir	S	Intravenous drip	100 Unk	Gilead
	Atorvastatin	C		10 Mg, Qhs	Not Reported
	Fluoxetine	C		Unk	Not Reported
	Trazodone	C		Unk	Not Reported
	Fluconazole	C		Unk	Not Reported
	Septra	C	Intravenous (not otherwise specified)	3 Doses	Not Reported
	Amiodarone	C	Intravenous (not otherwise specified)	Continous	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Doxycycline	C		Unk	Not Reported
	Naproxen	C		Unk	Not Reported
	Enoxaparin	C		90 Mg	Not Reported
	Acetaminophen	C		650 Mg Prn, Approx 9 Doses Admin	Not Reported
	Glucerna [Nutrients Nos]	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18153001	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0490179		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Decadron			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192196	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site	Remdesivir			S	Intravenous (not			Gilead

Extravasation; Infusion Site Oedema; Paravenous Drug Administration	0.9% Sodium Chloride 230ml			C	otherwise specified)				Not Reported
	Sterile Water For Injection 20ml			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192227	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192233	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192239	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192394	DIRECT	Y	DE			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Decreased; Cardiac Arrest; Cardio-Respiratory Arrest; Mental Status Changes; Pulseless Electrical Activity	Remdesivir		S	Intravenous bolus		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192759	DIRECT	Y				51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab	Y		S	Intravenous (not otherwise specified)		1 DAY	Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192763	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192766	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood	Remdesivir			S				Gilead

Creatinine Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192828	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0491871		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Unknown	100 Mg		Gilead
	Zosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192829	DIRECT	Y	DE			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Cardio-Respiratory Arrest; Dyspnoea; Dyspnoea; Lethargy; Pulseless Electrical Activity	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Oxycodone Immediate Release			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192831	DIRECT	Y				91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Renal Impairment	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192869	DIRECT	Y				53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Incorrect Product Administration Duration	Remdesivir	S	Intravenous bolus	Other Frequency:Once;	Gilead
	Remdesivir	S	Intravenous drip		Gilead
	Dexamethasone Sodium Phosphate	C			Not Reported
	Insulin Glargine	C			Not Reported
	Guafenesin Dextromethorphan	C			Not Reported
	Aspirin	C			Not Reported
	Albuterol Hfa	C			Not Reported
	Metoprolol Succinate	C			Not Reported
	Spironolactone	C			Not Reported
	Simvastatin	C			Not Reported
	Furosemide	C			Not Reported
	Benzonatate	C			Not Reported
	Ketorolac	C			Not Reported
	Atorvastatin	C			Not Reported
	Polyethylene Glycol	C			Not Reported
	Gabapentin	C			Not Reported
	Valsartan	C			Not Reported
	Olanzapine	C			Not Reported
	Ondansetron	C			Not Reported
	Enoxaparin	C			Not Reported
	Levothyroxine	C			Not Reported
	Pantoprazole	C			Not Reported
	Bisacodyl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18192920	DIRECT		LT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Remdesivir			S	Intravenous (not otherwise specified)	Frequency: Loading Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18193009	DIRECT	Y				70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disease Complication	Tocilizumab	Y		S	Intravenous (not otherwise specified)	Genentech
	Remdesivir	Y		S	Intravenous (not otherwise specified)	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18196257	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Eosinophilia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18196265	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Asthenia; Dyspnoea; Fall; Lung Infiltration	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab	Y		S	Intravenous (not otherwise specified)			Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18196270	DIRECT	Y				32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Veklury)	Y		S	Intravenous drip			Gilead
	Dexamethasone 6mg Iv/Po Daily			C				Not Reported
	Enoxaparin 40mg Sq Daily			C				Not Reported
	Iron Sucrose 300mg Iv Once			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18196277	DIRECT	Y	HO			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead
	Rocephin 1 Gm Q24h			C				Not Reported
	Doxycycline 100 Mg Po Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18198081	DIRECT	Y				76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Remdesivir			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Frequency: Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18198083	DIRECT	Y	DE			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Aspiration; Atrial Fibrillation; Cardiac Arrest; Cardioactive Drug Level Increased; Catheter Site Discharge; Cytokine Storm; Epistaxis; Gallbladder Disorder; Gallbladder Enlargement; Haemorrhage; Hepatic Function Abnormal;	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convelesent Plasma			C				Not Reported

Hypercoagulation; Hyperkalaemia; Hypernatraemia; Hypoxia; International Normalised Ratio Increased; Oliguria; Renal Impairment; Renal Tubular Necrosis; Swallow Study Abnormal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2020	18198084	DIRECT	Y				34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	17969833	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0477758		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Cardiac Arrest; Cardiac Arrest; Death; Dyspnoea; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Lispro Insulin			C		Unk		Not Reported
	Multivitamin [Vitamins Nos]			C		Unk		Not Reported
	Thiamine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18009496	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0481284		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Pulseless Electrical Activity	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Tocilizumab			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported
	Zosyn			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18119542	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0488629		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol;Ipratropium			C		Unk		Not Reported
	Restasis			C		Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Aspirin (E.C.)			C		Unk		Not Reported
	Fluticasone Propionate			C		Unk		Not Reported
	Miralax			C		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

	Labetalol	C	Unk	Not Reported
	Hydralazine	C	Unk	Not Reported
	Benzonatate	C	Unk	Not Reported
	Guaifenesin	C	Unk	Not Reported
	Acetaminophen	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18160555	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489906		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Shock; Transaminases Increased	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
	Remdesivir			S				Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg, Bid		Not Reported
	Cisatracurium			C	Intravenous (not otherwise specified)	37.5 Mg/Hr Continuous		Not Reported
	Fentanyl Citrate			C	Intravenous (not otherwise specified)	50 Mcg/Hr Continuously		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	50 Mcg/Kg/Min Continuously		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	5 Mcg/Min Continuously		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18195824	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-038247		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Liver Function Test Abnormal	Azithromycin			S	Oral	500mg Dosis Choque Y 250 Mg C/24h Mantenimiento		Aurobindo
	Azithromycin			S				Aurobindo

Remdesivir	S	Intravenous drip	100 Milligram, Once A Day	Not Reported
Remdesivir	S			Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	2 Gram, Once A Day	Not Reported
Ceftriaxone	S			Not Reported
Dexamethasone	S	Intravenous (not otherwise specified)	6 Milligram, Once A Day	Not Reported
Dexamethasone	S			Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Two Times A Day	Not Reported
Hydroxychloroquine	S			Not Reported
Midazolam	C	Unknown	Unk	Not Reported
Fentanyl	C	Unknown	Unk	Not Reported
Enoxaparin	C	Unknown	Unk	Not Reported
Cisatracurium	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Omeprazole	C	Unknown	Unk	Not Reported
Enalapril	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18197944	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Extravasation; Infusion Site Erythema; Infusion Site Oedema; Injection Site Extravasation	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198053	DIRECT	Y	HO			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir	S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198062	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Interrupted	Remdesivir (Eua Supply)			S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Doxycycline 100mg Iv			C				Not Reported
	Actaminophen 650mg Tablet			C				Not Reported
	Ceftriaxone 2gm Iv			C				Not Reported
	Dexamethasone 6mg Iv			C				Not Reported
	Fentanyl Iv			C				Not Reported
	Heparin Drip			C				Not Reported
	Regular Insulin Iv			C				Not Reported
	Norepinephrine Iv			C				Not Reported
	Oxycodone 10mg Tablet			C				Not Reported
	Propofol Infusion			C				Not Reported
	Rocuronium Iv			C				Not Reported
	Vasopressin Iv			C				Not Reported
	Nimbex Iv			C				Not Reported
	Midazolam Iv			C				Not Reported
	Zosyn Iv			C				Not Reported
	Cefepime Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198268	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Paravenous Drug Administration; Peripheral Swelling	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18198758	EXPEDITED (15-DAY)		LT, OT	US-GLAXOSMITHKLINE-US2020AMR167339		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Covid-19; Cytokine Storm; Disseminated Intravascular Coagulation; Haemoglobin Decreased; Hyperglycaemia; Hyperkalaemia; Hypotension; Iron Deficiency; Lactic Acidosis; Liver Injury; Pneumonia; Retroperitoneal Haematoma; Septic Shock; Shock Haemorrhagic; Swelling	Nicotine			S		Unk		Glaxosmithkline
	Levetiracetam			S		Unk		Glaxosmithkline
	Acetaminophen			S		Unk		Glaxosmithkline
	Dextromethorphan Hydrobromide			S		Unk		Glaxosmithkline
	Pantoprazole			S		Unk		Glaxosmithkline
	Lactulose			S		Unk		Glaxosmithkline
	Chlorhexidine Unknown Salt			S		Unk		Glaxosmithkline
	Ceftriaxone			S		Unk		Glaxosmithkline
	Ferrous Sulfate			S		Unk		Glaxosmithkline
	Duloxetine Hydrochloride			S		Unk		Not Reported
	Furosemide			S		Unk		Glaxosmithkline
	Docusate Sodium			S		Unk		Glaxosmithkline
	Lorazepam			S		Unk		Glaxosmithkline
	Gabapentin			S		Unk		Not Reported
	Midazolam			S		Unk		Not Reported
	Propofol			S		Unk		Not Reported
	Vancomycin			S		Unk		Not Reported
	Methylprednisolone			S		Unk		Not Reported
	Macrogol			S		Unk		Not Reported
	Cefepime Hydrochloride			S		Unk		Not Reported
	Meropenem			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Duoneb			S		Unk		Not Reported
	Suboxone			S		Unk		Not Reported

	Otezla			S		Unk			Not Reported
	Lovenox			S	Subcutaneous	Unk			Not Reported
	Fentanyl			S		Unk			Not Reported
	Ativan			S		Unk			Not Reported
	Sodium Polystyrene Sulfonate			S		Unk			Not Reported
	Buprenorphine Hydrochloride			S		Unk			Not Reported
	Ipratropium			S		Unk			Not Reported
	Salbutamol Sulfate			S		Unk			Not Reported
	Naloxone			S		Unk			Not Reported
	Apremilast			S		Unk			Not Reported
	Remdesivir			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18199596	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0492046		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Tachypnoea	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amlodipine			C				Not Reported
	Atenolol			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone Phosphate [Dexamethasone Sodium Phosphate]			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Hydromorphone			C				Not Reported
	Bisacodyl			C				Not Reported
	Lorazepam			C				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18199708	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0491549		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18200136	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0492114		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Hydroxyzine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18201362	DIRECT	Y				54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18201366	DIRECT	Y				21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18201404	DIRECT	Y	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Liver Function Test Abnormal; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous drip			Gilead
	Biktarvy			C				Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18201453	DIRECT	Y	HO			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:Given Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18201459	DIRECT	Y	DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Condition Aggravated; Epistaxis; Mouth Haemorrhage; Pao2/Fio2 Ratio Decreased; Septic Shock; Tracheobronchitis Bacterial	Remdesivir			S				Not Reported
	Lovenox			C				Not Reported
	Dexamethasone			C				Not Reported
	Iv Vitamin C			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18201465	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia	Remdesivir	S	Intravenous drip	Not Reported
	Remdesivir	S	Intravenous drip	Not Reported
	Remdesivir	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2020	18202563	DIRECT	Y	HO, OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholecystitis Acute; Cholelithiasis; Cholelithiasis; Haematuria; Hypercapnia; Hyperkalaemia; Metabolic Acidosis; Pco2 Increased; Pneumonia Staphylococcal; Pulmonary Oedema; Renal Impairment; Sputum Culture Positive; Staphylococcal Infection; Treatment Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17959115	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0474419		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Diarrhoea; Leukocytosis; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Plasma			C		291 Ml		Not Reported
	Acetaminofen			C	Oral	975 Mg		Not Reported
	Acetaminofen			C	Oral	650 Unk		Not Reported

Acetaminofen	C	Intravenous (not otherwise specified)	1000 Unk	Not Reported
Simethicone	C	Oral	15 Ml	Not Reported
Albuterol [Salbutamol]	C	Respiratory (inhalation)	180 Mcg	Not Reported
Albuterol [Salbutamol]	C		2.5 Mg	Not Reported
Azithromycin	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
Budesonide	C		0.25 Mg	Not Reported
Budesonide	C			Not Reported
Captopril	C	Oral	6.25 Mg	Not Reported
Captopril	C	Oral	12.5 Unk	Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)	1 G	Not Reported
Enoxaparin	C	Subcutaneous	40 Mg	Not Reported
Fentanyl	C	Intravenous (not otherwise specified)	Unk	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	20 Unk	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	40 Unk	Not Reported
Melatonin	C	Oral	6 Mg	Not Reported
Morphine	C	Intravenous (not otherwise specified)	2 Mg	Not Reported
Ondasetron [Ondansetron]	C	Intravenous (not otherwise specified)	Unk	Not Reported
Ondasetron [Ondansetron]	C			Not Reported
Pneumococcal Vaccine	C	Intramuscular	0.5 Ml	Not Reported
Potassium Chloride	C	Oral	40 Meq	Not Reported
Potassium Chloride	C	Oral	20 Unk	Not Reported
Potassium Chloride	C	Oral	40 Unk	Not Reported

	Sodium Chloride			C	Intravenous (not otherwise specified)	3 Ml				Not Reported
	Carvedilol			C	Oral	3.125 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	17989632	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0479491		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Cardio-Respiratory Arrest; Covid-19 Pneumonia; Hepatic Enzyme Increased; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Amiodarone			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Amiodarone			C	Oral	200 Mg		Not Reported
	Ascorbic Acid			C	Oral	500 Mg		Not Reported
	Cholecalciferol			C	Oral	1000 Iu		Not Reported
	Zinc Sulfate			C				Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	250 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	1000 Mcg/50ml Drip		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	50 Mg/250 Ml Drip		Not Reported
	Dexamethasone			C	Oral	200 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	90 Mg		Not Reported
	Sodium Chloride 0.9%			C	Intravenous (not otherwise specified)	50 Ml/Hr		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	8mg/250 Ml Drip		Not Reported
	Propofol			C	Intravenous (not	1000mg/100ml		Not Reported

			otherwise specified)		
Tocilizumab		C	Intravenous (not otherwise specified)	400 Mg	Not Reported
Albuterol Hfa		C	Respiratory (inhalation)	2 Puffs	Not Reported
Famotidine		C	Intravenous (not otherwise specified)	20 Mg	Not Reported
Furosemide		C	Intravenous (not otherwise specified)	20 Mg	Not Reported
Novolog		C	Subcutaneous	Per Ss	Not Reported
Levemir		C	Subcutaneous	10-30 Units	Not Reported
Insulin Regular [Insulin Bovine]		C	Intravenous (not otherwise specified)	10-15 Units	Not Reported
Labetalol		C	Intravenous (not otherwise specified)	10 Mg	Not Reported
Morphine		C	Intravenous (not otherwise specified)	2 Mg	Not Reported
Pantoprazole		C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Sodium Bicarbonate		C	Intravenous (not otherwise specified)	50 Meq	Not Reported
Succinylcholine [Suxamethonium]		C	Intravenous (not otherwise specified)	60 Mg	Not Reported
Zinc Sulfate		C	Oral	220 Mg	Not Reported
Duoneb		C	Unknown	3 Ml	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18027438	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482916		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemorrhagic Stroke; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported

	Calcium Chloride	C	Unk	Not Reported
	Cefepime	C	Unk	Not Reported
	Peridex [Chlorhexidine Gluconate]	C	Unk	Not Reported
	Dexamethasone	C	Unk	Not Reported
	Epinephrine	C	Unk	Not Reported
	Famotidine	C	Unk	Not Reported
	Furosemide	C	Unk	Not Reported
	Metoclopramide	C	Unk	Not Reported
	Midazolam	C	Unk	Not Reported
	Esmolol	C	Unk	Not Reported
	Fentanyl	C	Unk	Not Reported
	Insulin	C	Unk	Not Reported
	Norepinephrine	C	Unk	Not Reported
	Hypertonic Saline Solution	C	Unk	Not Reported
	Normal Saline	C	Unk	Not Reported
	Albumin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18055167	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0484150		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
	Rocephine			C	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported

	Guaifenesin			C	Oral	200 Mg				Not Reported
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	180 Mcg				Not Reported
	Albuterol [Salbutamol]			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18068869	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0485223		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Death; Oxygen Saturation Abnormal; Pneumomediastinum; Pneumothorax; Subcutaneous Emphysema	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Zosyn			S	Intravenous (not otherwise specified)	3.375 Mg		Not Reported
	Lipitor [Atorvastatin]			S	Oral	20 Mg		Not Reported
	Plasma			C				Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Amiodarone			C	Intravenous (not otherwise specified)	150 Mg		Not Reported
	Amiodarone			C	Intravenous (not otherwise specified)	0.5-1 Mg/Min		Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Cisatracurium			C				Not Reported
	Diltiazem			C	Intravenous (not otherwise specified)	5-15mg/Hr		Not Reported
	Enoxaparin			C	Subcutaneous	1 Mg/Kg		Not Reported
	Epoprostenol			C		160 Mcg/Hr Neb		Not Reported
	Ketamine			C	Intravenous (not otherwise specified)	5-40 Mcg/Kg/Min		Not Reported
	Lorazepam			C		1 Mg		Not Reported

Methylprednisolone	C			Not Reported
Midazolam	C			Not Reported
Norepinephrine	C			Not Reported
Pantoprazole	C			Not Reported
Piperacillin & Tazobactam	C			Not Reported
Rivaroxaban	C			Not Reported
Acetaminophen	C	Oral	1 G	Not Reported
Acetazolamide	C		500 Mg	Not Reported
Albumin	C	Intravenous (not otherwise specified)	25 G	Not Reported
Albumin	C	Intravenous (not otherwise specified)	25 Mg	Not Reported
Aspirin (E.C.)	C	Oral	81 Mg	Not Reported
Nimbex [Nimesulide]	C	Intravenous (not otherwise specified)	0.5-10 Mcg/Kg/Min	Not Reported
Plavix	C	Oral	75 Mg	Not Reported
Etomidate	C		20 Mg	Not Reported
Fentanyl	C	Intravenous (not otherwise specified)	2-250 Mcg/Hr	Not Reported
Furosemide	C		40-80 Mg, Ivp	Not Reported
Robitussin Dm	C	Oral	10 Ml	Not Reported
Heparin	C		3,000-4,000 Units, Ivp	Not Reported
Heparin	C	Intravenous (not otherwise specified)	50-2500 Units/Hr	Not Reported
Levemir	C	Subcutaneous	15 Units	Not Reported
Humalog	C	Subcutaneous	2-12 Units	Not Reported
Magnesium Sulfate	C	Intravenous (not otherwise specified)	2gm X2	Not Reported
Meropenem	C	Intravenous (not otherwise specified)	1 G	Not Reported
Meropenem	C	Intravenous (not otherwise specified)	1 Unk	Not Reported
Solu-Medrol	C		125 Mg	Not Reported

Solu-Medrol	C		60 Unk	Not Reported
Metoprolol	C	Oral	25 Mg	Not Reported
Metoprolol	C	Oral	50 Unk	Not Reported
Versed	C	Intravenous bolus	2 Mg	Not Reported
Versed	C	Intravenous (not otherwise specified)	1-12mg/Hr	Not Reported
Singulair	C	Oral	10 Mg	Not Reported
Morphine	C	Intravenous bolus	4 Mg	Not Reported
Morphine	C	Intravenous bolus	1 Unk	Not Reported
Morphine	C	Intravenous (not otherwise specified)	1-25mg/Hr	Not Reported
Levophed	C	Intravenous (not otherwise specified)	0.01-1 Mcg/Kg/Min	Not Reported
Protonix	C		40 Mg	Not Reported
Kcl	C	Intravenous (not otherwise specified)	30 Meq	Not Reported
Kcl	C	Intravenous (not otherwise specified)	20 Unk	Not Reported
Kcl	C	Intravenous (not otherwise specified)	40 Unk	Not Reported
Potassium Phosphates	C	Intravenous (not otherwise specified)	15 Mmol	Not Reported
Propofol	C	Intravenous (not otherwise specified)	5-80 Mcg/Kg/Min	Not Reported
Xarelto	C	Oral	20 Mg	Not Reported
Senokot-S	C	Oral	1 Tab	Not Reported
Sodium Bicarbonate	C		50 Meq	Not Reported
Succinylcholine [Suxamethonium]	C		100 Mg	Not Reported
Vecuronium	C		10 Mg	Not Reported
Vecuronium	C		10 Unk	Not Reported
Zinc Sulfate	C	Oral	220 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18078998	EXPEDITED (15-DAY)		DS, LT, OT	US-GILEAD-2020-0485015		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cetylpyridinium Chloride			C	Topical	0.05% Swab		Not Reported
	Chlorhexidine			C	Buccal	15 Ml, Bid		Not Reported
	Cisatracurium			C	Intravenous (not otherwise specified)	0.05 Mg/Kg		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	White Petrolatum			C		0.25-0.5 Inch		Not Reported
	Diltiazem			C	Intravenous (not otherwise specified)	2.5-15 Mg/Hr		Not Reported
	Enoxaparin			C	Subcutaneous	30 Mg		Not Reported
	Famotidine			C		Unk		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	50 Mcg		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Heparin			C		Unk		Not Reported
	Heparin			C	Intravenous (not otherwise specified)	1000 Units		Not Reported
	Heparin			C	Intravenous (not otherwise specified)	6800 Units		Not Reported
	Heparin			C	Intravenous (not otherwise specified)	1810 Units		Not Reported
	Insulin Lispro			C	Subcutaneous	1-18 Units		Not Reported
	Multivitamin Iron			C	Oral	15 Ml		Not Reported

	Mupirocin		C		Unk	Not Reported
	Polyethylene Glycol 3350		C		17 G	Not Reported
	Sennosides		C		10 Ml	Not Reported
	Propofol		C	Intravenous (not otherwise specified)	40 Mcg	Not Reported
	Midazolam		C	Intravenous (not otherwise specified)	2-6 Ml/Hr	Not Reported
	Norepinephrine		C	Intravenous (not otherwise specified)	16 Mg	Not Reported
	Aspirin (E.C.)		C	Oral	81 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18106190	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0486993		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol [Salbutamol Sulfate]			C	Respiratory (inhalation)	2 Puff		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Oral	81 Mg		Not Reported
	Atorvastatin			C	Oral	80 Mg		Not Reported
	Budesonide			C	Respiratory (inhalation)	0.5 Mg		Not Reported
	Fluticasone			C	Nasal	2 Spray		Not Reported
	Furosemide			C	Oral	40 Mg		Not Reported
	Guaifenesin			C	Oral	600 Mg		Not Reported
	Hydralazine			C		5 Mg		Not Reported
	Lorazepam			C	Intravenous (not otherwise specified)	1 Mg		Not Reported
	Losartan			C	Oral	100 Mg		Not Reported

Melatonin	C	Oral	6 Mg		Not Reported
Zinc Sulfate	C	Oral	220 Mg		Not Reported
Ivermectin	C	Oral	25500 Mcg		Not Reported
Thiamine	C	Intravenous (not otherwise specified)	200 Mg		Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	1250 Mg		Not Reported
Amlodipine	C	Oral	5 Mg		Not Reported
Ascorbic Acid	C	Intravenous (not otherwise specified)	3000 Mg		Not Reported
Azithromycin	C	Intravenous (not otherwise specified)	500 Mg		Not Reported
Cefepime	C	Intravenous (not otherwise specified)	2 G		Not Reported
Famotidine	C	Intravenous (not otherwise specified)	20 Mg		Not Reported
Heparin	C	Subcutaneous	7500 Units		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18124939	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489154		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18142372	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489769		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Valproic Acid			C					Not Reported
	Hydromorphone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18143338	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489779		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Liver Disorder; Oxygen Saturation Abnormal; Respiratory Failure; Septic Shock; Shock; Staphylococcal Bacteraemia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cisatracurium			C	Unknown	Unk		Not Reported
	Norepinephrine			C	Unknown	Unk		Not Reported
	Nafcillin			C	Unknown	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18146398	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489882		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Vancomycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Metronidazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201664	DIRECT	Y				88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201666	DIRECT	Y	RI			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Diarrhoea	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201688	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Infusion Related Reaction; Pruritus; Pruritus; Rash; Swelling Face; Urticaria	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201755	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201869	DIRECT	Y				86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Pruritus; Rash; Urticaria; Urticaria	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201872	DIRECT		OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201919	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extravasation; Infusion Site Bruising; Infusion Site Pain	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18201928	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Dispensing Error; Product Prescribing Issue; Product Use Issue	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202287	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure; Tachypnoea	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Frequency:Am;		Not Reported
	Plasma Protein Fraction (Plasma Protein Fraction 5% Inj)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202375	DIRECT	Y				77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202379	DIRECT	Y				91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospice Care	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202440	DIRECT	Y	RI, OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202446	DIRECT	Y				58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir (Eua) (Remdesivir (Eau)			S				Not Reported
	Remdesivir (Eua) (Remdesivir (Eau)			S				Not Reported
	Remdesivir (Eua) (Remdesivir (Eau)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202456	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202457	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202600	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Influenza; Pneumonia; Respiratory	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202603	DIRECT	Y	DE			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anxiety; Cardio-Respiratory Arrest; Dementia; Depression; Hyperlipidaemia; Hypertension; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18202801	DIRECT	Y	DE			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hyperkalaemia; Myocardial Infarction; Oliguria; Renal Failure; Ventricular Tachycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			S	Subcutaneous	Other Frequency:Once;		Genentech

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18206560	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bilevel Positive Airway Pressure; Brain Herniation; Brain Oedema; Cardiac Arrest; Family Stress; Haemodialysis; Haemoglobin Decreased; Pneumonia Staphylococcal; Pneumothorax;	Remdesivir			S				Not Reported
	Lovenox			C				Not Reported
	Dexamethaxone			C				Not Reported
	Tocilizumab			C				Not Reported
	Linezolid			C				Not Reported
	Cefepime			C				Not Reported

Procalcitonin Increased; Pulmonary Haemosiderosis; Renal Failure; Supraventricular Tachycardia; Suspected Covid-19; Tobacco User

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18206579	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Asthenia; Chest Discomfort; Chills; Diarrhoea; Dyspnoea; Liver Function Test Increased; Pneumonia; Productive Cough; Productive Cough; Pyrexia	Remdesivir	Y		S	Intravenous (not otherwise specified)		4 DAY	Gilead
	Acetaminophen 650 Mg Po Q6h Prn			C				Not Reported
	Albuterol Inhaler 2 Puffs			C				Not Reported
	Dexamethasone 6 Mg Po Daily			C				Not Reported
	Guaifenesin 100 Mg Po Q4h Prn			C				Not Reported
	Heparin 5000 Units Sq Q8h			C				Not Reported
	Insulin Sliding Scale Sq Ac And Hs			C				Not Reported
	Lantus Insulin 16 Units Sq Daily			C				Not Reported
	Melatonin 5 Mg Po Hs Prn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18206580	DIRECT	Y	OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone Injection			C				Not Reported
	Dexmedetomidine Infusion			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide Injection			C				Not Reported
	Loratadine Tablet			C				Not Reported
	Ondansetron Injection			C				Not Reported
	Sodium Chloride 0.9% With Kcl 20 Meq/L			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18206581	DIRECT	Y	OT			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2020	18206584	DIRECT	Y	HO			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen 325mg			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Atorvastatin 40mg			C				Not Reported
	Azithromycin 500mg			C				Not Reported
	Ceftriaxone 1g			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Docusate Sodium 100mg			C				Not Reported
	Heparin 5000 Units			C				Not Reported
	Insulin Glargine 40 Units			C				Not Reported
	Pantoprazole 40mg Tab			C				Not Reported
	Peg 3350 17g			C				Not Reported
	Propofol Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18001053	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0480857		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Ammonia Increased; Covid-19 Pneumonia; Renal Failure	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Cephalexin [Cefalexin]			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported

Meloxicam	C			Not Reported
Metoprolol	C			Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)	2 Mg, Qd	Not Reported
Decadron [Dexamethasone]	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
Enoxaparin	C	Subcutaneous	90 Mg, Qd	Not Reported
Folic Acid	C	Oral	1 Mg, Qd	Not Reported
Thiamine	C	Oral	100 Mg, Qd	Not Reported
Doxycycline	C	Oral	100 Mg	Not Reported
Midazolam	C	Intravenous (not otherwise specified)	Unk	Not Reported
Propofol	C		Unk	Not Reported
Lactulose	C		30 G, Qid	Not Reported
Lactulose	C		30 Mg, Q4hr	Not Reported
Levophed	C	Intravenous (not otherwise specified)	Titrated	Not Reported
Acetylcysteine	C			Not Reported
Albumin	C			Not Reported
Fentanyl	C	Intravenous (not otherwise specified)	Unk	Not Reported
Rifaximin	C	Oral	550 Mg, Bid	Not Reported
Heparin	C		Unk	Not Reported
Amiodarone	C	Intravenous (not otherwise specified)	Unk	Not Reported
Lantus	C	Subcutaneous	Unk	Not Reported
Levocarnitine	C	Oral	990 Mg, Q6h	Not Reported
Midodrine	C		5 Mg, Q8h	Not Reported
Midodrine	C		10 Unk	Not Reported
Multivitamin [Vitamins Nos]	C		Unk Unk, Qd	Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported

	Zosyn			C	Intravenous (not otherwise specified)	3.375 G, Q8h		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Insulin			C		Sliding Scale		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18084069	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0485112		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Levofloxacin			C				Not Reported
	Levaquin			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18094971	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477762		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nervousness	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C	Oral	81 Mg		Not Reported
	Atorvastatin			C	Oral	40 Mg		Not Reported

	Dexamethasone	C	Oral	6 Mg		Not Reported
	Enoxaparin	C	Subcutaneous	40 Mg		Not Reported
	Lisinopril	C	Oral	20 Mg		Not Reported
	Acetaminophen	C				Not Reported
	Albuterol Hfa	C	Respiratory (inhalation)	2 Puff		Not Reported
	Guaifenesin	C				Not Reported
	Ondansetron [Ondansetron Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Lidocaine	C	Topical	1 Patch		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18100843	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0487466		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C	Oral	325 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Famotidine			C	Oral	20 Mg		Not Reported
	Hydromorphone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207304	DIRECT	N	OT			93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carotid Artery Stenosis; Cerebral Ventricle Dilatation; Cerebrovascular Accident;	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not			Gilead

Decreased Appetite; Generalised Tonic-Clonic Seizure					otherwise specified)					
	Dorzolamide 2%			C						Not Reported
	Donepezil			C						Not Reported
	Finasteride			C						Not Reported
	Doxaxosin			C						Not Reported
	Dexamethasone Sodium Phosphate			C						Not Reported
	Levetiracetam			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207308	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207455	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Insulin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207489	DIRECT	Y				76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Interrupted	Remdesivir			S				Not Reported
	Lipitor			C				Not Reported
	Vitamin D			C				Not Reported
	Zinc			C				Not Reported

		Aspirin			C					Not Reported
		Azithromycin			C					Not Reported
		Lovenox			C					Not Reported
		Famotidine			C					Not Reported
		Methylprednisolone			C					Not Reported
		Metoprolol			C					Not Reported
		Zosyn			C					Not Reported
		Vancomycin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207503	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Genentech
	Remdesivir			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18207935	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Furosemide			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208178	EXPEDITED (15-DAY)		LT, OT	US-VALIDUS PHARMACEUTICALS			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Cytokine Storm; Disseminated Intravascular Coagulation; Haemoglobin Decreased; Hyperglycaemia; Hyperkalaemia; Hypotension; Iron Deficiency; Lactic Acidosis; Liver Injury; Retroperitoneal Haematoma; Septic Shock; Shock Haemorrhagic; Swelling	Furosemide			S	Unknown	Unk		Validus
	Metoprolol Tartrate			S	Unknown	Unk		Validus
	Lovenox			S	Subcutaneous	80 Mg, Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Midazolam			S	Unknown	Unk		Not Reported
	Levetiracetam			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Propofol			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Ferrous Sulfate			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Macrogol 4000			S	Unknown	Unk		Not Reported
	Cefepime Hydrochloride			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lactulose			S	Unknown	Unk		Not Reported
	Nicotine			S	Unknown	Unk		Not Reported
	Chlorhexidine			S	Unknown	Unk		Not Reported
	Dextromethorphan Hydrobromide			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Sodium Polystyrene Sulfonate			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

	Duoneb	S	Unknown	Unk		Not Reported
	Suboxone	S	Unknown	Unk		Not Reported
	Acetaminophen	S	Unknown	Unk		Not Reported
	Docusate Sodium & Senna	S	Unknown	Unk		Not Reported
	Otezla	S	Unknown	Unk		Not Reported
	Remdesivir	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208198	DIRECT	Y	HO			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Propofol			C				Not Reported
	Dopamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208206	DIRECT	Y	RI			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Tachycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208276	DIRECT	Y	DE			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Bilevel Positive Airway Pressure; Blood Loss Anaemia; Encephalopathy;	Remdesivir			S	Intravenous bolus			Gilead
	Heparin			C				Not Reported

Hypercapnia; Hypoxia; Melaena; Respiratory Failure; Troponin Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18208303	DIRECT	Y	OT			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18209029	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0492487		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Epistaxis; General Physical Health Deterioration; Mouth Haemorrhage; Respiratory Distress; Resuscitation; Septic Shock; Tracheobronchitis Bacterial	Remdesivir			S	Unknown			Gilead
	Morphine			C				Not Reported
	Xanax			C				Not Reported
	Decadron [Dexamethasone]			C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Tocilizumab			C		Unk		Not Reported
	Vitamin C [Ascorbic Acid]			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18209821	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0492484		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Unknown			Gilead
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Dexamethasone			C				Not Reported

Tocilizumab	C		Not Reported
Linezolid	C		Not Reported
Cefepime	C		Not Reported
Plasma	C		Not Reported
Zyvox	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18212257	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18212260	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18212266	DIRECT	Y	OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18212315	DIRECT	Y	HO, LT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arrhythmia; Asthenia;	Remdesivir (Veklury) Solution For Injection	Y		S	Intravenous drip			Gilead

Atrial Fibrillation; Cardio-Respiratory Arrest; Cough; Decreased Appetite; Dehydration; Dyspnoea; Pyrexia; Septic Shock; Vomiting	Guaifenesin 600 Mg Bid	C	Not Reported
	Zinc Acetate 50 Mg Po Daily	C	Not Reported
	Vitamin D3 2000 Units Po Daily	C	Not Reported
	Multivitamin With Minerals (Thera M Plus) 1 Tab Po Daily	C	Not Reported
	Calcium Carbonate 500 Mg Po Daily	C	Not Reported
	Lorazepam 0.5 Mg Hs Prn Anxiety	C	Not Reported
	Acetaminophen 650 Mg Po Q6h Prn Fever More Than 100.4 Degrees F	C	Not Reported
	Benzonatate 200 Mg Po Tid Prn Cough	C	Not Reported
	Carbamazepine 300 Mg Po Tid	C	Not Reported
	Dexamethasone 6 Mg Iv Daily	C	Not Reported
	Enoxaparin 80 Mg Subcutaneous Bid	C	Not Reported
	Famotidine 20 Mg Po Daily	C	Not Reported
	Lamotrigine 100 Mg Po Daily	C	Not Reported
	Olanzapine 5 Mg Im Hs Prn Agitation Due To Acute Delirium	C	Not Reported
	Acetaminophen 650 Mg Rectally Q6h Prn Fever	C	Not Reported
	Azithromycin 500 Mg Iv Daily	C	Not Reported
	Diltiazem 10 Mg Iv Push X 1	C	Not Reported
	Ceftriaxone 2 Gm Iv Q24 H	C	Not Reported
	Metoprolol Tartrate 10 Mg Iv Push X 1	C	Not Reported
	Dextrose 5% 1000 Ml At 50 Ml/Hr	C	Not Reported
	Propofol 10 Mg/Ml At 12.92 Ml/Hr	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18212322	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension	Remdesivir			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18212328	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2020	18212330	DIRECT	Y	DE			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Kidney Injury; Acute Myocardial Infarction; Acute Right Ventricular Failure; Anaemia; Gastrointestinal Haemorrhage; Haematoma; Heparin-Induced Thrombocytopenia; Pulmonary Embolism	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Zinc Sulfate 220 Mg Po Once Daily			C				Not Reported
	Pantoprazole 40 Mg Iv Bid			C				Not Reported
	Ezetimibe 10 Mg Po Once Daily			C				Not Reported
	Amiodarone 200 Mg Feed-Tube Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18210626	EXPEDITED (15-DAY)			US-GILEAD-2020-0492426		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone Sodium Phosphate			C		Unk		Not Reported

	Insulin Glargine	C	Not Reported
	Guaifenesin Dextromethorphan	C	Not Reported
	Aspirin	C	Not Reported
	Albuterol Hfa	C	Not Reported
	Metoprolol Succinate	C	Not Reported
	Spironolactone	C	Not Reported
	Simvastatin	C	Not Reported
	Furosemide	C	Not Reported
	Benzonatate	C	Not Reported
	Ketorolac	C	Not Reported
	Atorvastatin	C	Not Reported
	Polyethylene Glycol	C	Not Reported
	Gabapentin	C	Not Reported
	Valsartan	C	Not Reported
	Olanzapine	C	Not Reported
	Ondansetron	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2020	18212333	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2020	18212326	DIRECT	Y				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	17933655	EXPEDITED (15-DAY)		DE, DS, OT	US-GILEAD-2020-0474767		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Enoxaparin	C	Subcutaneous	40 Mg	Not Reported
	Duoneb	C	Respiratory (inhalation)	3 Ml	Not Reported
	Pantoprazole	C	Oral	40 Mg	Not Reported
	Sodium Chloride	C			Not Reported
	Propofol	C	Intravenous (not otherwise specified)	Titrated	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported
	Albuterol [Salbutamol]	C	Respiratory (inhalation)	2 Puffs	Not Reported
	Insulin	C	Intravenous (not otherwise specified)	10 Units	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18085583	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486599		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dissection; Death; Depressed Level Of Consciousness; Hypertension; Hypoxia; Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Labetalol			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported

Plasma	C		Unk	Not Reported
Oxygen	C			Not Reported
Chlorhexidine	C	Oral	15 Ml, Bid	Not Reported
Acetaminophen	C			Not Reported
Acetaminophen	C			Not Reported
Pravastatin	C		40 Mg, Qd	Not Reported
Insulin Lispro	C	Subcutaneous	Per Scale	Not Reported
Buspirone	C		30 Mg, Bid	Not Reported
Senna Laxative And Docusate Sodium	C	Oral	2 Dosage Form, Bid	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	2 G, Q8h	Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	1750 Mg, Q8h	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported
Citrate Of Magnesia	C		300 Ml, Qd	Not Reported
Lorazepam	C	Intravenous (not otherwise specified)	2 Mg	Not Reported
Morphine	C	Intravenous (not otherwise specified)	4 Mg	Not Reported
Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
Enoxaparin	C	Subcutaneous	130 Mg	Not Reported
Venlafaxine	C		37.5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18163576	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490618		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Flushing; Infusion Related Reaction;	Remdesivir			S	Intravenous (not	Unk		Gilead

Respiratory Failure				otherwise specified)		
	Remdesivir		S	Intravenous (not otherwise specified)	200 Mg	Gilead
	Albuterol		C			Not Reported
	Acetaminophen		C		Unk	Not Reported
	Ceftriaxone		C			Not Reported
	Clindamycin		C			Not Reported
	Dexamethasone		C			Not Reported
	Famotidine		C			Not Reported
	Motrin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18164409	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2020315657		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Death; Oxygen Saturation Decreased; Pneumomediastinum; Pneumothorax; Subcutaneous Emphysema	Zosyn			S	Intravenous (not otherwise specified)	3.375 Mg, Daily		Pfizer
	Lipitor			S	Oral	20 Mg, Daily		Pfizer
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Single (200 Mg, Once)		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, 1x/Day (Qd)		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Acetazolamide			C		Unk		Not Reported
	Albumin			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported
	Aspirin (E.C.)			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

Epoprostenol	C	Unk	Not Reported
Etomidate	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Humalog	C	Unk	Not Reported
Kcl	C	Unk	Not Reported
Ketamine	C	Unk	Not Reported
Levemir	C	Unk	Not Reported
Levophed	C	Unk	Not Reported
Lorazepam	C	Unk	Not Reported
Magnesium Sulfate	C	Unk	Not Reported
Methylprednisolone	C	Unk	Not Reported
Meropenem	C	Unk	Not Reported
Metoprolol	C	Unk	Not Reported
Midazolam	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Nimbex [Nimesulide]	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Piperacillin & Tazobactam	C	Unk	Not Reported
Plasma	C	Unk	Not Reported
Plavix	C	Unk	Not Reported
Potassium Phosphates	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Protonix	C	Unk	Not Reported
Rivaroxaban	C	Unk	Not Reported
Robitussin Dm	C	Unk	Not Reported
Senokot-S	C	Unk	Not Reported

Singulair	C	Unk	Not Reported
Sodium Bicarbonate	C	Unk	Not Reported
Solu-Medrol	C	Unk	Not Reported
Succinylcholine [Suxamethonium]	C	Unk	Not Reported
Tocilizumab	C	Unk	Not Reported
Vecuronium	C	Unk	Not Reported
Versed	C	Unk	Not Reported
Xarelto	C	Unk	Not Reported
Zinc Sulfate	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18213717	DIRECT	Y	DE			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Atrial Fibrillation; Cardiac Disorder; Condition Aggravated; Dialysis; General Physical Health Deterioration; Hypercapnia; Hyperhidrosis; Hypoventilation; Pyrexia; Renal Failure; White Blood Cell Count Increased	Eau Remdesivir			S				Not Reported
	Cyanocobalamin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Quetiapine			C				Not Reported
	Ramelteon			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported
	Amiodarone			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18213731	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Remdesivir (Eua Supply)	S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin 10mg Po	C				Not Reported
	Lisinopril 20mg Po	C				Not Reported
	Azithromycin 500mg Iv	C				Not Reported
	Ceftriaxone 2g Iv	C				Not Reported
	Dexamethason 6mg Iv	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18213939	DIRECT	Y				45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18217005	DIRECT	Y	OT			19 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cholelithiasis	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18217009	DIRECT	Y				71 YR	Female	AFG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18217015	DIRECT	Y				35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous bolus			Gilead
	Redesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18217020	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Movement Disorder; Incoherent; Loss Of Consciousness	Remdesivir (Eua)			S	Intravenous bolus		5 DAY	Gilead
	Convalescent Plasma			S	Intravenous bolus	Other Frequency:Once;		Unknown
	Tylenol 650 Mg			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Nicotine Patch 21mg			C				Not Reported
	Ondansetron 4 Mg			C				Not Reported
	Senna			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18217042	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Amiodarone 360mg/200ml			C				Not Reported
	Zofran Iv 4mg			C				Not Reported
	Norepinephrine 8mg/250ml			C				Not Reported
	Diltiazem 10mg Iv			C				Not Reported
	Azithromycin 500mg Iv			C				Not Reported
	Unasyn 3g Once			C				Not Reported
	Potassium Chloride 10meq			C				Not Reported
	Magnesium Sulfate 2g			C				Not Reported
	Lovenox 40mg			C				Not Reported
	Rocephin 2g Iv Daily			C				Not Reported
	Rocuronium 100mg Iv Once			C				Not Reported
	Propofol Iv			C				Not Reported
	Famotidine 20mg Iv Q12hrs			C				Not Reported
	Fentanyl 50mcg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2020	18217632	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir 100mg			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18082608	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0485063		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hyperkalaemia; Lactic Acidosis; Renal Impairment	Remdesivir			S	Intravenous drip	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Norepinephrine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zosyn			C		Unk		Not Reported
	Solumedrol			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Methylprednisolone			C				Not Reported
	Vancomycin			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Arixtra			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Propofol			C				Not Reported
	Rocuronium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18120871	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489059		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute	Remdesivir			S	Intravenous (not	100 Mg		Gilead

Respiratory Distress Syndrome; Covid-19; Renal Failure			otherwise specified)		
	Aspirin (E.C.)	C	Oral	81 Mg, Qd	Not Reported
	Cefazolin	C	Intravenous (not otherwise specified)	1 G, Bid	Not Reported
	Heparin	C	Subcutaneous	5000 Units	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	10 Mg, Qd	Not Reported
	Nystatin	C	Topical	100,000 Units	Not Reported
	Protonix [Omeprazole]	C	Intravenous (not otherwise specified)	40 Mg, Bid	Not Reported
	Quetiapine	C	Oral	400 Mg, Bid	Not Reported
	Sodium Bicarbonate	C	Oral	1300 Mg, Q6h	Not Reported
	Voriconazol	C	Intravenous (not otherwise specified)	400 Mg, Bid	Not Reported
	Precedex	C	Intravenous (not otherwise specified)		Not Reported
	Fentanyl	C	Intravenous (not otherwise specified)		Not Reported
	Insulin	C	Intravenous (not otherwise specified)		Not Reported
	Ketamine	C	Intravenous (not otherwise specified)		Not Reported
	Midazolam	C	Intravenous (not otherwise specified)		Not Reported
	Propofol	C	Intravenous (not otherwise specified)		Not Reported
	Vasopressin	C	Intravenous (not otherwise specified)		Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18147798	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489943		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Propofol			C	Intravenous (not otherwise specified)	Titrate		Not Reported
	Insulin			C	Subcutaneous	Titrate		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Titrate		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Titrate		Not Reported
	Vecuronium			C	Intravenous (not otherwise specified)	Titrate		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18187887	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0491666		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Morphine			C				Not Reported
	Valsartan			C				Not Reported
	Pantoprazole			C				Not Reported
	Gabapentin			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18215513	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Betamethasone			S	Unknown	Unk		Taro
	Nitric Oxide			S		Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217628	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Creatinine Increased; Thrombocytopenia	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (Tocilizumab 20mg/Ml Inj, Soln, 20ml)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217677	DIRECT	Y				50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217730	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217841	DIRECT	Y	RI			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217864	DIRECT	Y				50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217888	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18217972	EXPEDITED (15-DAY)			US-GILEAD-2020-0492646		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218092	EXPEDITED (15-DAY)			US-GILEAD-2020-0492652			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218239	DIRECT	Y	HO			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported
	Buspar			C				Not Reported
	Lovenox			C				Not Reported
	Prilosec			C				Not Reported
	Probiotic			C				Not Reported
	Robitussin Ac			C				Not Reported
	Tessalon			C				Not Reported
	Tylenol			C				Not Reported
	Ultram			C				Not Reported
	Zofran			C				Not Reported
	Ventolin Inhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218244	EXPEDITED (15-DAY)			US-GILEAD-2020-0492655			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218393	EXPEDITED (15-DAY)			US-GILEAD-2020-0492659			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218818	EXPEDITED (15-DAY)			US-GILEAD-2020-0492664			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18218951	EXPEDITED (15-DAY)			US-GILEAD-2020-0492665			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18219329	EXPEDITED (15-DAY)		OT	ES-BAUSCH-BL-2020-024976		64 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Dexametasona			S	Unknown			Bausch And Lomb
	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)	200 Mg Loading Dose 1st Day		Not Reported
	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)	100 Mg/24 H 4 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18219835	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0492912		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Kidney Injury; Acute Right Ventricular Failure; Chronic Kidney Disease; Death; Delirium; Haematoma; Heparin-Induced Thrombocytopenia; Hypernatraemia; Hypotension; Hypoxia; Pulmonary Embolism; Renal Cortical Necrosis	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Ezetimibe			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18221114	DIRECT	Y	DE			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Dyspnoea; Oliguria; Pyrexia; Troponin Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18221206	DIRECT	Y	DE			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiopulmonary Failure; Fall; Haemothorax; Rib Fracture; Shock; Therapy Cessation; Thrombocytopenia	Remdesivir			S				Not Reported
	Cefepime			C				Not Reported
	Fluconazole			C				Not Reported
	Metronidazole			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Albuterol			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate Sodium			C				Not Reported
	Dornase Alpha Nebulizer			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Hydrocortisone			C				Not Reported
	Insulin			C				Not Reported
	Lidocaine 5%			C				Not Reported
	Thiamine			C				Not Reported
	Zinc			C				Not Reported
	Precedex			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18221211	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Norepinephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Carbamezepine (Home Med)			C				Not Reported
	Midazolam Drip			C				Not Reported
	Nimbex Drip			C				Not Reported
	Zonisamide (Home Med)			C				Not Reported
	Vancomycin Iv			C				Not Reported
	Azithromycin			C				Not Reported
	Pip/Tazo			C				Not Reported
	Furosemide			C				Not Reported

Famotidine				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2020	18221234	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Condition Aggravated; Haemodialysis; Oxygen Saturation Decreased; Shock	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	17877683	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469518		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Arrest; Covid-19 Pneumonia; Endotracheal Intubation; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S		Unk		Gilead
	Tocilizumab			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Enoxaparin			C	Subcutaneous	40		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	20		Not Reported
	Insulin 2			C		Unk		Not Reported
	Lorazepam			C				Not Reported
	Phenylephrine			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported

	Acetaminophen			C						Not Reported
	Plasma			C			Convalescant			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18089790	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0486578		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Covid-19 Pneumonia; Hyperkalaemia; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)	10 Mg		Not Reported
	Lovenox			C	Subcutaneous	30 Mg		Not Reported
	Glimepiride			C	Oral	2 Mg		Not Reported
	Irbesartan			C	Oral	75 Mg		Not Reported
	Ivermectin			C	Oral	15000 Mg, Once		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Rocephin [Ceftriaxone]			C	Intravenous (not otherwise specified)	2 G		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18109413	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0488454		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C	Oral	6 Mg		Not Reported
	Albuterol Sulfate And Ipratropium Bromide			C		Unk		Not Reported

	Duoneb			C	Respiratory (inhalation)	3 Ml			Not Reported
	Atorvastatin			C	Oral	20 Mg			Not Reported
	Furosemide			C		20-40 Mg			Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg			Not Reported
	Lisinopril			C	Oral	20 Mg			Not Reported
	Nifedipine			C	Oral	60 Mg			Not Reported
	Nitroglycerine			C	Transdermal	2 %			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18143289	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489884		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Remdesivir			S	Unknown	Unk		Gilead
	Vancomycin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Zosyn			C				Not Reported
	Dexamethasone			C				Not Reported
	Plasma			C		Unk		Not Reported
	Morphine			C	Intravenous (not otherwise specified)	2 Mg		Not Reported
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Benztropine [Benzatropine]			C	Intramuscular	1 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Haloperidol			C	Intravenous (not otherwise specified)	3 Mg		Not Reported
	Heparin			C	Subcutaneous	5000 Units		Not Reported
	Quetiapine			C	Oral	12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18158585	EXPEDITED (15-DAY)		LT	US-ROCHE-2658622		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardio-Respiratory Arrest; Septic Shock	Tocilizumab			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose Of Tocilizumab Prior To Sae Onset 13/Jul/2020 At 21.54		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose Of Remdesivir Prior To Sae Onset 16/Jul/2020 At 21.27		Not Reported
	Acetaminophen			C				Not Reported
	Acetaminophen			C				Not Reported
	Acetaminophen			C				Not Reported
	Insulin Lispro			C		Bedtime		Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Lispro			C				Not Reported
	Ondansetron			C				Not Reported
	Ondansetron			C				Not Reported
	Norco			C				Not Reported
	Lisinopril			C				Not Reported
	Morphine			C				Not Reported
	Atorvastatin			C				Not Reported
	Insulin Detemir			C				Not Reported
	Insulin Regular			C				Not Reported
	Insulin Regular			C				Not Reported
	Insulin Regular			C				Not Reported
	Insulin Regular			C				Not Reported
	Fentanyl			C				Not Reported
	Rocuronium			C				Not Reported
	Rocuronium			C				Not Reported
	Enoxaparin			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Norepinephrine			C				Not Reported
	Norepinephrine			C				Not Reported
	Furosemide			C				Not Reported
	Furosemide			C				Not Reported
	Furosemide			C				Not Reported
	Propofol			C				Not Reported
	Propofol			C				Not Reported
	Midazolam			C				Not Reported

		Midazolam			C					Not Reported
		Midazolam			C					Not Reported
		Flolan			C					Not Reported
		Ketamine			C					Not Reported
		Heparin			C					Not Reported
		Hydrocortisone			C					Not Reported
		Vancomycin			C					Not Reported
		Cefepime			C					Not Reported
		Vasopressin			C					Not Reported
		Sodium Bicarbonate			C					Not Reported
		Ampicillin;Sulbactam			C					Not Reported
		Metronidazole			C					Not Reported
		Hydralazine			C					Not Reported
		Labetalol			C					Not Reported
		Dexamethasone			C					Not Reported
		Ibuprofen			C					Not Reported
		Ibuprofen			C					Not Reported
		Doxycycline			C					Not Reported
		Vancomycin			C					Not Reported
		Cefepime			C					Not Reported
		Albuterol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18178418	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0490927		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200/100mg, Qd		Gilead
	Benzonatate			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18220868	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-258626			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Foetal Exposure During Pregnancy; Intraventricular Haemorrhage Neonatal; Low Birth Weight Baby; Neonatal Respiratory Distress Syndrome; Patent Ductus Arteriosus; Premature Baby	Hydroxychloroquine			S	Transplacental			Sun
	Azithromycin			S	Transplacental			Sun
	Betamethasone			S	Transplacental			Taro
	Nitric Oxide			S	Transplacental			Not Reported
	Remdesivir			S	Transplacental			Not Reported
	Tocilizumab			S	Transplacental			Not Reported
	Magnesium Sulfate			C	Unknown			Not Reported
	Propofol			C	Transplacental			Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221668	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Interrupted	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221733	DIRECT	Y	OT			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone (Ceftriaxone Na 2gm/Vil Inj)			S	Intravenous (not otherwise specified)	Other Strength:2gm/Vil;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221737	DIRECT	Y	OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)		Not Reported
	Ceftriaxone (Ceftriaxone Na 2gm/Vil Inj)			S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221785	DIRECT	Y	CA, HO			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221818	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Disease Progression; Respiratory Depression	Remdesivir (Eua)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221819	DIRECT	Y	LT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased; Multiple Organ Dysfunction Syndrome	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221909	DIRECT	Y	DE			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; General Physical Health Deterioration; Haemodialysis; Therapy Interrupted	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18221912	DIRECT	Y				77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222037	DIRECT	Y	DE			121 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222159	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Respiratory Depression	Remdesivir (Eua) (Remdesivir (Eua))	S	Other Route:Iv	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222188	DIRECT	Y	LT, OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Cytokine Storm; Hepatic Enzyme Increased; Systemic Inflammatory Response Syndrome	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:Iv		Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222232	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222472	EXPEDITED (15-DAY)			US-GILEAD-2020-0492727		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222490	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Doxycycline			C				Not Reported
	Fentanyl			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222500	EXPEDITED (15-DAY)			US-GILEAD-2020-0492732		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222631	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Hepatomegaly; Platelet Count Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18222993	DIRECT	Y				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18223074	DIRECT	Y	DE			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Arrest; Pneumonia; Pneumonia Bacterial; Pneumonia Viral; Pulmonary Oedema; Pulse Absent; Respiratory Failure	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18223561	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; International Normalised Ratio Increased; Prothrombin Time Ratio Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18226194	DIRECT	Y	DE			84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus			Gilead
	Amlodipine 5mg Daily			C				Not Reported
	Azithromycin 500mg Ivpb Q24h			C				Not Reported
	Cefepime 1gm Q8h Ivpb			C				Not Reported
	Metronidazole 500mg Ivpb Q8h			C				Not Reported

	Quetiapine 25mg Qhs	C	Not Reported
	Dexamethasone 6mg Ivp Daily	C	Not Reported
	Ascorbic Acid 1500mg Tid	C	Not Reported
	Zinc Sulf 220mg Daily	C	Not Reported
	Aspirin 81mg Daily	C	Not Reported
	Heparin 5000u Sq Q12h	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2020	18272871	DIRECT					30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Product Use In Unapproved Indication; Rash Maculo-Papular	Remdesivir Loading Dose 200mg, Then 100mg			S		Other Dose:Loading Dose 200mg;Other Route:Iv	10 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18077754	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0485067		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Solu-Medrol			C		Unk		Not Reported
	Solu-Medrol			C	Intravenous (not otherwise specified)	40 Unk		Not Reported
	Amlodipine			C	Oral	10 Mg		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G		Not Reported

	Lovenox Hp	C	Subcutaneous	40 Mg		Not Reported
	Lasix [Furosemide]	C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Seroquel	C	Oral	25 Mg		Not Reported
	Plasma	C				Not Reported
	Micafungin	C				Not Reported
	Linezolid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18225445	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05194		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18226420	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18227578	DIRECT	Y				76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Alkaline	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported
	Adult Clinimix E Ptn			C				Not Reported
	Albuterol			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported

Phosphatase Increased; Blood Calcium Decreased; Blood Glucose Increased; Blood Urea Increased; Hypoxia; Platelet Count Decreased	Budesonide			C					Not Reported
	Ceftriaxone			C					Not Reported
	Codeine/Guaifenesin			C					Not Reported
	Dexamethasone			C					Not Reported
	Dexmedetomidine In Ns			C					Not Reported
	Duloxetine Dr			C					Not Reported
	Enoxaparin			C					Not Reported
	Famotidine			C					Not Reported
	Furosemide			C					Not Reported
	Gabapentin			C					Not Reported
	Levothyroxine			C					Not Reported
	Lorazepam			C					Not Reported
	Morphine Iv			C					Not Reported
	Ondansetron			C					Not Reported
	Potassium Phosphates In Ns			C					Not Reported
	Ropinirole			C					Not Reported
	Tocilizumab			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18227743	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen 650 Mg Po Q6h Prn			C				Not Reported
	Ascorbic Acid 500 Mg Po Bid			C				Not Reported
	Azithromycin 500 Mg Po Daily			C				Not Reported
	Robitussin Ac 10 Ml Po Q8h Prn			C				Not Reported
	Enoxaparin 40 Mg Sc Daily			C				Not Reported
	Famotidine 20 Mg Po Bid			C				Not Reported
	Furosemide 40 Mg Iv Bid			C				Not Reported
	Methylprednisolone 40 Mg Iv Tid			C				Not Reported
	Thiamine Mononitrate 100 Mg Po Daily			C				Not Reported
	Zinc Sulfate 220 Mg Po Bid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228013	DIRECT	Y	OT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Blood Bilirubin Increased; Respiratory Failure	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228063	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228253	DIRECT	Y	OT			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Adderall Xr			C				Not Reported
	Dexamethasone			C				Not Reported
	Mucinex			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228257	DIRECT					51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Sweats; Rash Pruritic; Skin Disorder	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228262	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Vascular Access Complication	Remdesivir			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18228331	DIRECT	Y	OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Hydrocodone/Apap			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229187	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05211			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Betamethasone			S	Transplacental	Unk		Lupin
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229192	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05219			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During	Hydroxychloroquine			S	Transplacental	Unk		Lupin

Pregnancy; Low Birth Weight Baby	Betamethasone			S	Transplacental	Unk			Lupin
	Remdesivir			S	Transplacental	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229193	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05215			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Betamethasone			S	Transplacental	Unk		Lupin
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229194	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05214		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18229202	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05216		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18231682	DIRECT	Y	OT			38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Infusion Related Reaction	Remdesivir	Y		S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18231686	DIRECT	Y	OT			90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Carvedilol 6.25 Mg			C				Not Reported
	Furosemide 10mg/Ml			C				Not Reported
	Ceftriaxone 6.25 Mg			C				Not Reported
	Dexamethasone 6 Mg			C				Not Reported
	Hydroxyzine 25 Mg			C				Not Reported
	Multivitamin			C				Not Reported
	Pantoprazole 40 Mg			C				Not Reported
	Tramadol 50 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2020	18231733	DIRECT	Y	OT			84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18104269	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0488298		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Albumin			C				Not Reported

	Cisatracurium	C	Not Reported
	Epoprostenol	C	Not Reported
	Fentanyl	C	Not Reported
	Insulin Nph [Insulin Isophane Bovine]	C	Not Reported
	Lactobacillus	C	Not Reported
	Midazolam	C	Not Reported
	Norepinephrine	C	Not Reported
	Pantoprazole	C	Not Reported
	Phenylephrine	C	Not Reported
	Piperacillin / Tazobactam	C	Not Reported
	Propofol	C	Not Reported
	Sodium Polystyrene Sulfonate	C	Not Reported
	Tocilizumab	C	Not Reported
	Vasopressin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18195636	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0491801		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased; Incorrect Product Administration Duration	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Keppra			C	Unknown	Unk		Not Reported
	Keppra			C		Unk		Not Reported
	Magnesium Sulfate			C	Unknown	Unk		Not Reported
	Decadron [Dexamethasone Acetate]			C	Unknown	Unk		Not Reported
	Decadron [Dexamethasone Acetate]			C		Unk		Not Reported
	Heparin			C	Unknown	Unk		Not Reported
	Lasix [Furosemide Sodium]			C	Unknown	Unk		Not Reported
	Lopressor			C	Unknown	Unk		Not Reported
	Lopressor			C	Unknown	Unk		Not Reported
	Lopressor			C		Unk		Not Reported

	Humulin R	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Hydromet [Homatropine Methylbromide;Hydrocodone Bitartrate]	C	Unknown	Unk	Not Reported
	Zosyn	C	Unknown	Unk	Not Reported
	Flomax [Morniflumate]	C	Unknown	Unk	Not Reported
	Colace	C	Unknown	Unk	Not Reported
	Lactated Ringers	C	Unknown	Unk	Not Reported
	Klor-Con	C		Unk	Not Reported
	Atorvastatin	C			Not Reported
	Dextrose 5%	C		Unk	Not Reported
	Donepezil	C		Unk	Not Reported
	Enzalutamide	C			Not Reported
	Insulin Regular Hm	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Polyethylene Glycol 3350	C			Not Reported
	Potassium Chloride	C			Not Reported
	Tamsulosin	C			Not Reported
	Hydrocodone/Homatropine	C			Not Reported
	Nacl	C			Not Reported
	Piperacillin Tazobactam Pa	C			Not Reported
	Sodium Phosphate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232036	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0493594		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232298	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Cardiomyopathy; Fluid Overload; Hypotension; Shock	Remdesivir	S	Gilead
	Calcium Gluconate 1g Iv X1	C	Not Reported
	Ceftriaxone 1 G Iv Daily	C	Not Reported
	Chlorhexidine 0.12% Mouthwash 15 Ml Bid	C	Not Reported
	Dexamethasone 20 Mg Iv Daily	C	Not Reported
	Dextrose 25 G Iv X1	C	Not Reported
	Famotidine 20 Mg Iv Nightly	C	Not Reported
	Furosemide 100 Mg Iv X1	C	Not Reported
	Furosemide 60 Mg Iv X1	C	Not Reported
	Heparin 7500 Units Subq Q8h	C	Not Reported
	Magnesium 2g Iv X1	C	Not Reported
	Midazolam Continuous Infusion - Titrated	C	Not Reported
	Sodium Bicarb 50 Meq Iv X1	C	Not Reported
	Fentanyl Continuous Infusion	C	Not Reported
	Heparin Continous Infusion For Crrt	C	Not Reported
	Dialysate Solution	C	Not Reported
	Norepinephrine Continuous Infusion Titrated	C	Not Reported
	Vasopressin Continuous Infusion Titrated	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232341	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Feeling Abnormal; Nausea	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232342	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232383	DIRECT	Y				55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua)			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232472	DIRECT	Y	DE			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported
	Dexamethaxone			C				Not Reported
	Lovenox			C				Not Reported
	Cefepime			C				Not Reported
	Melatonin			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Levophed			C				Not Reported
	Vancomycin			C				Not Reported
	Versed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232564	DIRECT	Y	HO			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Liver Function Test	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

Increased; Protein Total Decreased; Therapy Cessation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232627	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Depression	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232688	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (Tocilizumab 20mg/Ml Inj, Soln, 20ml)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232701	DIRECT	Y				81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir (Eua) (Remdesivir (Eua)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232705	DIRECT	Y	OT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232713	DIRECT	Y				82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Pain; Infusion Related Reaction; Infusion Site Pain	Remdesivir (Eua)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232714	DIRECT	Y				78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232734	DIRECT	Y	DE			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Therapy Non-Responder	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232751	DIRECT	Y	DE			58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; General Physical Health Deterioration; Hypotension; Pulmonary	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

Embolism; Sinus Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232802	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18232972	DIRECT	Y	DE			94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Diltiazem			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18233281	DIRECT	Y	DE			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebellar Stroke; Embolic Stroke; Escherichia Infection; Ischaemic Stroke; Mechanical Ventilation Complication; Pneumonia Bacterial; Tracheomalacia; Transfusion; Urinary Tract Infection	Remdesivir			S				Not Reported
	Lovenox			C				Not Reported
	Levophed			C				Not Reported
	Vasopressin			C				Not Reported
	Versed			C				Not Reported
	Fentanyl			C				Not Reported
	Dexamethaxone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Cefepime			C				Not Reported

	Vancomycin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18233292	DIRECT		DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospice Care; Transfusion	Remdesivir			S				Not Reported
	Lovenox			C				Not Reported
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxine			C				Not Reported
	Iv Vitamin C			C				Not Reported
	Lasix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18233294	DIRECT	Y	DE, OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Agitation; Anxiety; Cardiac Arrest; Cardiac Failure Chronic; Transfusion; Urine Output Decreased; Ventricular Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18233523	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1076672		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	400 Milligram, Bid On Day 1		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid On Days 2-5		Mylan
	Azithromycin			S	Unknown	500 Milligram On Day 1		Mylan
	Azithromycin			S	Unknown	250 Milligram On Days 2-5		Mylan

	Bivalirudin	S	Unknown	03-0.4 Microg/Kg/H	Mylan
	Methylprednisolone	S	Unknown	40 Milligram, Bid On Days 1-3	Mylan
	Anakinra	S	Unknown	100 Milligram, Q6h On Days 1-5	Mylan
	Anakinra	S	Unknown	100 Milligram Every 12 Hours On Days 5-10	Mylan
	Anakinra	S	Unknown	100 Milligram, Qd On Days 11-13	Mylan
	Remdesivir	S	Unknown	200 Milligram On Day 1	Mylan
	Remdesivir	S	Unknown	100 Milligram, Qd Days 2-5	Mylan
	Nitric Oxide	S	Unknown	Unk	Mylan
	Thrombate Iii	S	Unknown	Unk	Mylan
	Epinephrine	C		Unk	Mylan
	Vancomycin	C	Unknown	Unk	Mylan
	Cefepime	C	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18233679	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disorientation; Pneumonia Legionella; Respiratory Arrest; Unresponsive To Stimuli	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported
	Azithromycin (Azithromycin 500mg/Vil Inj)			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin (Azithromycin 500mg/Vil Inj)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18235056	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0493938		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dextromethorphan;Guaifenesin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Tiotropium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18240613	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18240720	DIRECT	Y	LT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18240859	DIRECT	Y				37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Pre-Eclampsia; Transaminases Increased	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18241024	DIRECT	Y	OT			15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir 200 Mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100 Mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported
	Pepcid			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2020	18241656	DIRECT	Y	DE, OT			15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir 200mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100 Mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported

	Ceftriaxone	C		Not Reported
	Dexamethasone	C		Not Reported
	Lovenox	C		Not Reported
	Pepcid	C		Not Reported
	Ibuprofen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18240630	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Heart Rate Decreased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18240637	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18240657	DIRECT	Y				24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Rash Erythematous	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18240659	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia	Remdesivir			S	Intravenous (not			Not Reported

					otherwise specified)				
	Azithromycin			C					Not Reported
	Cefepime			C					Not Reported
	Vancomycin			C					Not Reported
	Convalescent Plasma			C					Not Reported
	Methylprednisolone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2020	18240853	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2020	18200636	EXPEDITED (15-DAY)		DE, LT, OT	US-ROCHE-2664389		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Hyperlipidaemia; Intentional Product Use Issue; International Normalised Ratio Increased; Off Label Use; Prothrombin Time Prolonged; Thrombocytopenia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous bolus	Qd For 4 Days		Not Reported
	Diprivan			S	Intravenous (not otherwise specified)	For 4 Days		Not Reported
	Lovenox			S	Subcutaneous	For 10 Days		Not Reported
	Decadron			C		8 Jul 2020 , 22 Jul 2020		Not Reported
	Precedex			C				Not Reported
	Ativan			C		11 Jul 2020,1 Aug 2020		Not Reported
	Glucerna			C		10 Jul 2020, 3 Aug 2020		Not Reported
	Humulin R			C		10 Jul 2020, 03 Aug 2020		Not Reported
	Rocephin			C		08 Jul 2020, 12 Aug 2020		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C		08-Jul-2020		Not Reported
	Normal Saline			C				Not Reported
	Morphine			C		08 Jul 2020, 26 Jul 2020		Not Reported

Vecuronium	C	08-Jul-2020	Not Reported
Tylenol	C	08 Jul 2020, 13 Jul 2020	Not Reported
Albuterol Sulfate Hfa	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236900	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259769		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Sun
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236901	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259771		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Sun
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236902	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259770			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Sun
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236903	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259766		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Sun
	Remdesivir			S	Unknown	Unk		Not Reported
	Betamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18236906	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259772			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Low; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Sun
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18240662	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18240667	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not			Gilead

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18240673	DIRECT	Y	DE			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18240678	DIRECT	Y				78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl Pca			C				Not Reported
	Iohexol			C				Not Reported
	Norepinephrine			C				Not Reported
	Olanzapine Zydis			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
	Valproic Acid			C				Not Reported
	Vancomycin			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18240683	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alanine	Remdesivir			S	Intravenous drip			Gilead

Aminotransferase Increased	Azithromycin			C					Not Reported
	Ceftriaxone			C					Not Reported
	Dexamethasone			C					Not Reported
	Acetaminophen			C					Not Reported
	Albuterol Inhaler			C					Not Reported
	Ondansetron			C					Not Reported
	Ipratropium Inhaler			C					Not Reported
	Enoxaparin			C					Not Reported
	Atorvastatin			C					Not Reported
	Quetiapine			C					Not Reported
	Pantoprazole			C					Not Reported
	Amlodipine			C					Not Reported
	Aspirin			C					Not Reported
	Venlafaxine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2020	18241077	DIRECT	Y	DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Condition Aggravated; Hospice Care; Hypoxia	Remdesivir			S				Not Reported
	Diltiazem			C				Not Reported
	Ceftriaxone			C				Not Reported
	Metoprolol			C				Not Reported
	Vancomycin			C				Not Reported
	Cefepime			C				Not Reported
	Morphine			C				Not Reported
	Gabapentin			C				Not Reported
	Amiodarone			C				Not Reported
	Dexamethasone			C				Not Reported
	Insulin			C				Not Reported
	Lovenox			C				Not Reported
	Vitamin C			C				Not Reported
	Lasix			C				Not Reported
	Seroquel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	17941111	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0473733		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased; Respiratory Failure	Remdesivir	S	Unknown	100 Mg, Qd	Gilead
	Aspirin [Acetylsalicylic Acid]	C	Oral	81 Mg, Qd	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G, Qd	Not Reported
	Chlorhexidine	C	Oral	Unk	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
	Famotidine	C	Oral	20 Mg, Bid	Not Reported
	Furosemide	C	Intravenous (not otherwise specified)	20 Mg, Q8h	Not Reported
	Metoclopramide	C	Intravenous (not otherwise specified)	5 Mg, Q8h	Not Reported
	Mvi [Vitamins Nos]	C		Unk	Not Reported
	Senna-S [Docusate Sodium; Sennoside A+B]	C	Oral	Unk, Bid	Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Artificial Tears [Hypromellose]	C		Unk	Not Reported
	Dexmedetomidine	C	Intravenous (not otherwise specified)		Not Reported
	Fentanyl	C	Intravenous (not otherwise specified)		Not Reported
	Heparin	C	Intravenous (not otherwise specified)		Not Reported
	Insulin	C	Intravenous (not otherwise specified)		Not Reported
	Midazolam	C	Intravenous (not otherwise specified)		Not Reported
	Oxygen	C			Not Reported
	Cotrimoxazole	C		7 Doses	Not Reported
	Tocilizumab	C			Not Reported
	Plasma	C			Not Reported
	Ativan	C			Not Reported
	Precedex	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18143288	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489707		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Alprazolam			C	Oral	0.5 Mg		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Atorvastatin			C	Oral	40 Mg		Not Reported
	Cholecalciferol			C	Oral	2000 Units		Not Reported
	Famotidine			C	Oral	Unk		Not Reported
	Fluticasone			C	Respiratory (inhalation)	1 Puff		Not Reported
	Heparin			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Lisinopril			C		Unk		Not Reported
	Ivermectin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Aspirin (E.C.)			C	Oral	81 Mg		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Thiamine			C		Unk		Not Reported

	Zinc Gluconate			C		Unk				Not Reported
	Oxygen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18146369	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489902		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Bacteraemia; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Atrial Thrombosis; Blood Creatinine Increased; Fibrin D Dimer Increased; Hypotension; Ischaemic Hepatitis; Klebsiella Bacteraemia; Oxygen Saturation Decreased; Pulmonary Embolism; Pulmonary Hypertension; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Calcium Chloride			C	Intravenous (not otherwise specified)	1 G		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	10 Mg		Not Reported
	Lantus			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Insulin			C	Subcutaneous	Sliding Scale		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Phenylephrine			C				Not Reported
	Esmolol			C				Not Reported
	Epoprostenol			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Epinephrine			C				Not Reported
	Vasopressin			C				Not Reported
	Meropenem			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18146974	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0489897		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18150636	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490192		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18194439	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0491564		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dyspnoea; Hypertension	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Insulin			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Aspirin (E.C.)			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Dextromethorphan Hbr & Guaifenesin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

Ezetimibe	C	Unk	Not Reported
Fenofibrate	C	Unk	Not Reported
Hydrochlorothiazide	C	Unk	Not Reported
Magnesium Oxide	C	Unk	Not Reported
Metoprolol	C	Unk	Not Reported
Sertraline	C	Unk	Not Reported
Valsartan	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18200875	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0492145		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardio-Respiratory Arrest; Covid-19; Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Oxygen			C				Not Reported
	Oxycodone			S	Oral	5 Mg		Not Reported
	Naloxone			C		0.4 Mg		Not Reported
	Norepinephrine			C				Not Reported
	Acetaminophen			C	Oral	1 G		Not Reported
	Albuterol Hfa			C	Respiratory (inhalation)	2 Puff		Not Reported
	Ascorbic Acid			C	Oral	500 Mg		Not Reported
	Aspirin (E.C.)			C	Oral	81 Mg		Not Reported
	Bisacodyl			C	Rectal	10 Mg		Not Reported
	Dexamethasone			C	Oral	6 Mg		Not Reported
	Docusate			C	Oral	100 G		Not Reported
	Heparin			C	Subcutaneous	5000 Units		Not Reported
	Insulin Lispro			C	Subcutaneous	2 Units		Not Reported
	Ipratropium Bromide/Albuterol Sulfate			C	Respiratory (inhalation)	3 Ml		Not Reported
	Lactobacillus			C	Oral	1 G		Not Reported

Levothyroxine	C	Oral	75 Mcg		Not Reported
Lidocaine	C	Transdermal	5%		Not Reported
Mupirocin	C	Topical	2%		Not Reported
Pantoprazole	C	Oral	20 G		Not Reported
Polyethylene	C	Oral	17 G		Not Reported
Propranolol	C	Oral	20 G		Not Reported
Senna Acutifolia	C	Oral	8.6 Mg		Not Reported
Tocopherol	C	Oral	Unk		Not Reported
Piperacillin/Tazobactam	C	Intravenous (not otherwise specified)	4.5 G		Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	500 Mg		Not Reported
Vitamin D3	C	Oral	2000 Units		Not Reported
Zinc Sulphate	C	Oral	220 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241824	DIRECT	Y	DE			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241829	DIRECT	Y	DE			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241833	DIRECT	Y	DE			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Remdesivir	S		Gilead
	Methylprednisolone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241838	DIRECT	Y				81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18241943	DIRECT	Y	DE			99 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Dyspnoea; General Physical Health Deterioration; Hypoxia; Respiratory Failure; Respiratory Failure; Sars-Cov-2 Test Positive	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242010	DIRECT	Y				31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Gabapentin			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242095	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; General Physical Health Deterioration; Hypotension; Renal Impairment	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242123	DIRECT	Y				79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Daily For Five Day;		Gilead
	Metoprolol			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lovenox			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Azithromycin			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Roflumilast			C				Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Esomeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242382	NON-EXPEDITED			US-009507513-2008USA012812		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Betamethasone Acetate (+) Betamethasone Sodium Phosphate			S		Unk		Merck

	Hydroxychloroquine Sulfate			S		Unk				Not Reported
	Remdesivir			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242643	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0493990		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Hypotension; Vomiting	Remdesivir			S	Intravenous bolus	200 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Precedex			C				Not Reported
	Diltiazem			C				Not Reported
	Docusate			C				Not Reported
	Duloxetine			C				Not Reported
	Enoxaparin			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Furosemide			C				Not Reported
	Haloperidol			C				Not Reported
	Hydralazine			C				Not Reported
	Lantus			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lactobacillus			C				Not Reported
	Lorazepam			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Methylprednisolone			C				Not Reported
	Potassium Chloride			C				Not Reported
	Lyrica			C				Not Reported
	Seroquel			C				Not Reported
	Terazosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242684	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0493944		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tracheomalacia	Remdesivir			S	Unknown			Gilead
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Levophed			C				Not Reported

		Vasopressin			C					Not Reported
		Versed			C					Not Reported
		Fentanyl			C					Not Reported
		Dexamethasone			C					Not Reported
		Dexmedetomidine			C					Not Reported
		Cefepime			C					Not Reported
		Vancomycin			C					Not Reported
		Plasma			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242847	NON-EXPEDITED			US-009507513-2009USA002560		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Dexamethasone			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Remdesivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242935	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg-1st Dose 100;		Gilead
	Iohexol			C				Not Reported
	Enoxaparin			C				Not Reported
	Ondansetron			C				Not Reported
	Sumatriptan			C				Not Reported
	Dexamethasone			C				Not Reported
	Prochlorperazine			C				Not Reported
	Topiramate			C				Not Reported
	Pantoprazole			C				Not Reported
	Gabapentin			C				Not Reported
	Loperamide			C				Not Reported
	Potassium Chloride			C				Not Reported
	Levofloxacin			C				Not Reported
	Fentanyl			C				Not Reported
	Tramadol			C				Not Reported

	Promethazine				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242940	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Transcription Medication Error; Wrong Schedule	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242953	DIRECT	Y	DE			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atelectasis; Pleural Effusion	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18242996	DIRECT	Y				42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Administration Error; Product Dispensing Error	Remdesivir 100 Mg/20 Ml Vial	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243057	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Blood Creatinine Increased; Pneumonia; Refusal Of Treatment By Relative;	Remdesivir Eua			S				Not Reported

Sepsis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243060	DIRECT	Y	DE			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Interrupted	Remdesivir Injectable Vial			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Cefepime 29m Iv Q12hr			C				Not Reported
	Vancomycin 1.25gm Iv Q24hr			C				Not Reported
	Quetiapine12.5mgqhs			C				Not Reported
	Allopun'Nol 100mg Daily			C				Not Reported
	Escitalopram 10mg Daily			C				Not Reported
	Famotidine 20mg Iv Bid			C				Not Reported
	Heparin 5000 Units Sq Q8hr			C				Not Reported
	Levothyroxine 75mcg Ng Daily			C				Not Reported
	Fentanyl 50mcg/Hour			C				Not Reported
	Norepinephrine 1-5mcg/Minute			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243069	DIRECT	Y	RI			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased	Remdesivir			S				Not Reported
	Enoxaparin			C				Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C				Not Reported
	Lohexol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243377	NON-EXPEDITED			US-009507513-2009USA002561		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Betamethasone Acetate (+) Betamethasone Sodium			S		Unk		Merck

	Phosphate									
	Hydroxychloroquine Sulfate			S		Unk				Not Reported
	Remdesivir			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243690	NON-EXPEDITED			US-009507513-2009USA002563		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Betamethasone Acetate (+) Betamethasone Sodium Phosphate			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Remdesivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243712	NON-EXPEDITED			US-009507513-2009USA002562		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Betamethasone Acetate (+) Betamethasone Sodium Phosphate			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Remdesivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18243905	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0494015		15 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
	Albuterol Hfa			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Pepcid [Famotidine]			C				Not Reported
	Ibuprofen			C				Not Reported
	Zofran [Ondansetron Hydrochloride]			C				Not Reported
	Toradol			C				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18244298	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0493932		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Malaise	Remdesivir			S	Unknown	Unk		Gilead
	Dexamethasone			C				Not Reported
	Lovenox Hp			C				Not Reported
	Cefepime			C				Not Reported
	Melatonin			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Levophed			C				Not Reported
	Vancomycin			C				Not Reported
	Versed			C				Not Reported
	Decadron [Dexamethasone]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18244351	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0493949		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead
	Plasma			C				Not Reported
	Vitamin C [Ascorbic Acid]			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Dexamethasone			C				Not Reported

		Azithromycin			C						Not Reported
		Ceftriaxone			C						Not Reported
		Lasix [Furosemide]			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2020	18244368	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0493992		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Chest Discomfort; Death; Dyspnoea; Hypoxia; Pharyngeal Swelling; Swollen Tongue; Wheezing	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18021816	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482431		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blindness; Eye Irritation; Nausea	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18197631	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0492074		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Respiratory Failure	Remdesivir			S	Unknown	100 Mg		Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Ipratropium			C				Not Reported
	Lorazepam			C				Not Reported
	Momentasone			C				Not Reported
	Morphine			C				Not Reported

Nifedipine	C				Not Reported
Hydromorphone	C				Not Reported
Albuterol Hfa	C				Not Reported
Cefepime	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245603	DIRECT	Y	HO			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245608	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous drip		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245683	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous bolus		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245689	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18245947	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Melatonin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
	Zinc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246632	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Respiratory Disorder; Therapy Interrupted	Remdesivir			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246934	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Condition	Remdesivir 100mg/10ml	Y		S	Intravenous (not otherwise specified)			Gilead

Aggravated	Remdesivir 100mg/10ml	Y	S	Intravenous (not otherwise specified)					Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246946	DIRECT		OT			30 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246948	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18246951	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous bolus			Not Reported
	Doxycycline			C				Not Reported
	Ceftriaxone			C				Not Reported
	Linezolid			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Cholecalciferol			C				Not Reported
	Melatonin			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin B-1			C				Not Reported
	Zinc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247040	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-259767			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Unknown	Unk		Sun
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247045	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247056	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18247954	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0494141		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Product Administration Error	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18249561	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0494103		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Norepinephrine			C		Unk		Not Reported
	Vasopressin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Entresto			C				Not Reported
	Prednisone			C				Not Reported
	Calcium Gluconate			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Chlorhexidine			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Dextrose			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Sodium Bicarbonate			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Dialysate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18250002	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0494211		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Covid-19; Glomerular Filtration Rate Decreased; Respiratory Failure	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Ascorbic Acid	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Cholecalciferol	C		Unk	Not Reported
	Dexamethasone	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Iohexol	C		Unk	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Olanzapine Zydus	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Propofol	C		Unk	Not Reported
	Valproic Acid [Valproate Sodium]	C		Unk	Not Reported
	Vancomycin	C		Unk	Not Reported
	Zinc Sulfate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18250038	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0494220		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; General Physical Health Deterioration	Remdesivir			S	Unknown	Unk		Gilead
	Decadron A			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Plasma			C				Not Reported
	Diltiazem			C				Not Reported
	Ceftriaxone			C				Not Reported
	Metoprolol			C				Not Reported
	Vancomycin			C				Not Reported
	Cefepime			C				Not Reported
	Morphine			C				Not Reported
	Gabapentin			C				Not Reported

		Dexamethasone			C						Not Reported
		Insulin			C						Not Reported
		Lovenox Hp			C						Not Reported
		Lasix [Furosemide]			C						Not Reported
		Seroquel			C						Not Reported
		Amiodarone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18251927	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18251989	DIRECT	Y	OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Drug-Induced Liver Injury	Remdesivir	Y		S	Intravenous drip			Not Reported
	Budesonide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Ipratropium-Albuterol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18252008	DIRECT	Y				72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18252015	DIRECT	Y				51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18252115	DIRECT	Y				63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Tachypnoea	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2020	18252327	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir 100mg/10ml	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg/10ml	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	17950557	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475632		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Intravenous (not	200 Mg, Unk		Gilead

				otherwise specified)		
	Remdesivir		S	Intravenous (not otherwise specified)	100 Mg, Unk	Gilead
	Ceftriaxone		C			Not Reported
	Doxycycline		C			Not Reported
	Insulin		C			Not Reported
	Fentanyl		C			Not Reported
	Methylprednisolone		C			Not Reported
	Norepinephrine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18133298	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1070709		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Liver Function Test Abnormal; Off Label Use	Azithromycin			S	Oral	500mg Loading Dose And 250 Mg Q/24h Maintenance Dose		Mylan
	Azithromycin			S				Mylan
	Hidroxicloroquina /00072601/			S	Oral	400 Mg C/12h Dc Y 200mg C/12 Mant		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Dexametasona /00016001/			S	Intravenous (not otherwise specified)	6 Milligram, Qd (6mg C/24)		Mylan
	Dexametasona /00016001/			S				Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd (2g/24h)		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Remdesivir			S	Intravenous drip	100 Milligram, Qd (100 Mg C/24h)		Mylan
	Remdesivir			S				Mylan
	Midazolam			C		Unk		Mylan
	Fentanilo /00174601/			C		Unk		Mylan
	Enoxaparina			C		Unk		Mylan
	Cisatracurio			C		Unk		Mylan
	Paracetamol			C		Unk		Mylan

	Omeprazol /00661201/			C		Unk			Mylan
	Enalapril			C		Unk			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18152968	EXPEDITED (15-DAY)			US-GILEAD-2020-0490304		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Abnormal; Headache	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18188158	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0491648		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Injury; Death; Hypoxia; Mental Status Changes; Septic Shock	Remdesivir			S	Unknown	Unk		Gilead
	Hydromorphone			C		Unk		Not Reported
	Glycopyrrolate [Glycopyrronium]			C		Unk		Not Reported
	Tocilizumab			C		400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18242236	EXPEDITED (15-DAY)			US-GILEAD-2020-0494000		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Product Administration Error	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18251210	EXPEDITED (15-DAY)			US-GILEAD-2020-0494125			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252493	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Pain	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252581	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Guaifenesin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252592	DIRECT	Y	OT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol Inhaler			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported

	Famotidine	C		Not Reported
	Fluticasone Inhalation	C		Not Reported
	Guaifenesin	C		Not Reported
	Quetiapine	C		Not Reported
	Sucralfate	C		Not Reported
	Zinc	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252757	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous drip			Gilead
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin			C				Not Reported
	Topic Lidocaine Patch			C				Not Reported
	Methylprednisolone			C				Not Reported
	Metoprolol			C				Not Reported
	Nifedipine			C				Not Reported
	Pantoprazole			C				Not Reported
	Rosuvastatin			C				Not Reported
	Vancomycin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252824	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin 81mg			C				Not Reported
	Ceftriaxone 1gm			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone 10mg			C				Not Reported
	Enoxaparin 40mg			C				Not Reported
	Prenatal Vitamin			C				Not Reported

	Pantoprazole 40mg			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18252900	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haematoma; Acute Respiratory Failure; Bradycardia; Fibrin D Dimer Increased; General Physical Health Deterioration; Oxygen Saturation Decreased; Pneumonia; Pulse Absent; Sepsis	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18255466	EXPEDITED (15-DAY)			US-GILEAD-2020-0494604		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18255468	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0494372		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18256320	DIRECT	Y	DE			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardio-Respiratory Arrest; Dysphagia; Sars-Cov-2 Antibody Test Negative; Treatment Noncompliance	Remdesivir	S		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18256327	DIRECT	Y	OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetylcysteine			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Clonazepam			C				Not Reported
	Dexamethasone			C				Not Reported
	Dicyclomine			C				Not Reported
	Donepezil			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Hydrocodone-Acetaminophen			C				Not Reported
	Imipramine			C				Not Reported
	Venlafaxine			C				Not Reported
	Lidocaine Patch			C				Not Reported
	Ipratropium-Albuterol			C				Not Reported
	Levetiracetam			C				Not Reported
	Levothyroxine			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2020	18256437	DIRECT	Y	DE			98 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not			Gilead

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18115973	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0488810		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead
	Solu-Medrol			C	Intravenous (not otherwise specified)	40 Mg, Q8h		Not Reported
	Albuterol Hfa			C				Not Reported
	Eliquis			C				Not Reported
	Mylanta Original			C	Oral	60 Ml, Prn		Not Reported
	Milk Of Magnesia			C	Oral	30 Ml, Qd, Prn		Not Reported
	Zofran [Ondansetron]			C	Intravenous (not otherwise specified)	4 Mg, Prn Every 6 Hours		Not Reported
	Tylenol			C	Oral	500 Mg, Prn Every 6 Hrs		Not Reported
	Solumedrol			C				Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Ventolin Hfa			C		Unk		Not Reported
	Ventolin Hfa			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Lopressor			C	Oral	Unk		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Lactated Ringers			C		Unk		Not Reported
	Magnesium Sulphate [Magnesium Sulfate]			C		Unk		Not Reported
	Levaquin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18161149	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1814314		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Disorder	Hidroxicloroquina (2143a)	S	Oral	400 Mg C / 12h Dc And 200mg C / 12 Maint	Teva
	Hidroxicloroquina (2143a)	S			Teva
	Azitromicina (7019a)	S	Oral	500mg Shock Dose And 250 Mg C / 24h Maintenance	Not Reported
	Azitromicina (7019a)	S			Not Reported
	Dexametasona (722a)	S	Intravenous (not otherwise specified)	6mg C/24	Not Reported
	Dexametasona (722a)	S			Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily;	Not Reported
	Ceftriaxona (501a)	S			Not Reported
	Remdesivir (10009a)	S	Intravenous drip	100 Mg C/24h	Not Reported
	Remdesivir (10009a)	S			Not Reported
	Midazolam (2256a)	C			Not Reported
	Fentanilo (1543a)	C			Not Reported
	Enoxaparina (2482a)	C			Not Reported
	Cisatracurio (2738a)	C			Not Reported
	Paracetamol (12a)	C			Not Reported
	Omeprazol (2141a)	C			Not Reported
	Enalapril (2142a)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18256844	EXPEDITED (15-DAY)		OT	ZA-ROCHE-2675309			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Intentional Product Use Issue; Off Label Use	Actemra			S	Intravenous (not otherwise specified)	Frequency: Stat		Not Reported
	Remdesivir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257033	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Haemodialysis	Remdesivir	S		Gilead
	Remdesivir	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257143	DIRECT	Y				86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257182	DIRECT	Y				48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257351	DIRECT	Y	DE			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea Increased; General Physical Health Deterioration; Hepatic Enzyme Increased; Renal Impairment	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (Tocilizumab 20mg/Ml Inj,Soln,10ml)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257366	DIRECT	Y				45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Transaminases Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257379	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257412	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hyperhidrosis; Nausea	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257422	DIRECT	Y	RI			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257428	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bradycardia; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone (Dexamethasone 6mg Tab)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257433	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257438	DIRECT	Y	RI			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported
	Atorvastatin (Atorvastatin Ca 20mg Tab)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257445	DIRECT	Y	HO			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Normal; Blood Urea Increased; Disease Progression	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (Tocilizumab 20mg/Ml Inj, Soln, 10ml)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257470	DIRECT	Y	RI			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257514	DIRECT	Y	RI			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Cessation	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257549	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir			S			4 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257665	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257667	DIRECT	Y				63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Coldness; Limb Discomfort; Skin Discolouration	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257671	DIRECT	Y				83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Flushing; Hyperhidrosis	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257740	DIRECT	Y	DE			91 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Complication; Respiratory Failure	Remdesivir			S				Not Reported
	Calcium Acetate			C				Not Reported
	Nimbex			C				Not Reported
	Folic Acid			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Dornase Alpha			C				Not Reported
	Doxycycline			C				Not Reported
	Epinephrine			C				Not Reported
	Escitalopram			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Heparin			C				Not Reported
	Hydralazine			C				Not Reported

	Hydroxychloroquine			C					Not Reported
	Levemir			C					Not Reported
	Isosorbide			C					Not Reported
	Ketamine			C					Not Reported
	Victoza			C					Not Reported
	Mycophenolate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257863	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Lovenox			C				Not Reported
	Sodium Chloride			C				Not Reported
	Tylenol			C				Not Reported
	Miralax			C				Not Reported
	Refresh Drops			C				Not Reported
	Norvasc			C				Not Reported
	Zithromax			C				Not Reported
	Rocephin			C				Not Reported
	Lisinopril			C				Not Reported
	K-Cl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257866	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypertension	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Norepinephrine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Enoxaparin			C				Not Reported
	Gabapentin			C				Not Reported
	Loratidine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257906	DIRECT	Y	HO			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue; Product Storage Error	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Albuterol Hfa			C				Not Reported
	Dexamethasone 6 Mg			C				Not Reported
	Metoprolol Succinate 25 Mg Tab			C				Not Reported
	Ampicillin-Sulbactam 3 Gm Iv			C				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported
	Budesonide-Formoterol 160-4.5 Mcg/Puff			C				Not Reported
	Ceftriaxone 1 Gm			C				Not Reported
	Insulin Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Rivaroxaban 20 Mg Tab			C				Not Reported
	Sodium Bicarbonate 650 Mg Tab			C				Not Reported
	Zinc Sulfate 220 Mg Capsule			C				Not Reported
	Cholecalciferol (Vit D3) 5000 Units Capsule			C				Not Reported
	Ascorbic Acid 1000 Mg Tab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18257981	DIRECT	Y				47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18258013	DIRECT	Y	HO			18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported

	Remdesivir	Y		S	Intravenous (not otherwise specified)					Not Reported
	Dexamethasone 6mg Po Daily			C						Not Reported
	Enoxaparin 40 Mg Sq Daily			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18259128	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0494609		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin (E.C.)			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Guaifenesin			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18259195	EXPEDITED (15-DAY)			US-GILEAD-2020-0494612			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18261466	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous drip			Not Reported
	Allopurinol			C				Not Reported
	Amlodipine			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18261491	DIRECT	Y	OT			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir For Injection			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18261492	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Not Reported
	Vitamin D			C				Not Reported
	Doxazosin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Aspart			C				Not Reported
	Lisinopril			C				Not Reported
	Sertraline			C				Not Reported
	Valproic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18261497	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Fexofenadine			C				Not Reported
	Glipizide			C				Not Reported
	Insulin Aspart			C				Not Reported
	Metoprolol			C				Not Reported
	Sertraline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18261500	DIRECT	Y	OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Aspart			C				Not Reported
	Levothyroxine			C				Not Reported
	Liraglutide			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Oxycodone			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18261507	DIRECT		OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Not Reported
	Mycophenolate			C				Not Reported
	Sodium Bicarb			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Calcitriol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2020	18263218	DIRECT	Y	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2020	18261518	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2020	18261521	DIRECT	Y	OT			57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Heart Rate Decreased; Therapy Cessation	Remdesivir	S	Intravenous drip		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2020	18261523	DIRECT	Y	LT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Chlorohexidine Gluconate Po			C				Not Reported
	Mupirocin 2% Nasal App			C				Not Reported
	Sodium Bicarbonate 150 Meq Civ			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Azithromycin 500 Mg Iv Daily			C				Not Reported
	Dexamethasone 6 Mg Iv Daily			C				Not Reported
	Fentanyl Civ			C				Not Reported
	Midazolam Civ			C				Not Reported
	Vasopressin 0.4 Units/Min Civ			C				Not Reported
	Enoxaparin 40 Mg Subq			C				Not Reported
	Heparin Civ			C				Not Reported
	Ativan 2 Mg Per Tube Q6h			C				Not Reported
	Oxycodone 10 Mg Per Tube Q6h			C				Not Reported
	Vancomycin 1750 Mg Iv Once			C				Not Reported
	Zosyn 4.5g Iv Once			C				Not Reported
	Rocuronium 100 Mg Iv Once			C				Not Reported
	Midazolam 3 Mg Iv Once			C				Not Reported
	Etomidate 15 Mg Iv Once			C				Not Reported
	Fentanyl 100 Mcg Iv Once			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2020	18261528	DIRECT	Y	HO			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	17956925	EXPEDITED (15-DAY)		DE, HO, LT, OT	NL-AUROBINDO-AUR-APL-2020-031011			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Barotrauma; Pneumonia	Furosemide			S	Unknown	Unk		Aurobindo
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Remifentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ceftriaxon			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Movicolon			C	Oral	Unk		Not Reported
	Nadroparin			C	Subcutaneous	Unk		Not Reported
	Cisatracurium			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Supradyn			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18045095	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484021		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardio-Respiratory Arrest; Covid-19 Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Oxygen			C				Not Reported
	Enoxaparin			C	Subcutaneous	30 Mg, Qd		Not Reported
	Linezolid			C	Oral	600 Mg Q12h		Not Reported

	Cefepime	C	Intravenous (not otherwise specified)	2 G Q12h		Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	512 Mg, Once		Not Reported
	Levofloxacin	C	Intravenous (not otherwise specified)	750 Mg Q48h		Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	1250 Mg Q24h		Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Atorvastatin	C	Oral	40 Mg, Qd		Not Reported
	Pantoprazole	C	Oral	40 Mg, Qd		Not Reported
	Memantine	C	Oral	5 Mg, Qhs		Not Reported
	Carvedilol	C	Oral	12.5 Mg, Bid		Not Reported
	Carvedilol	C				Not Reported
	Aspirin (E.C.)	C	Oral	81 Mg, Qd		Not Reported
	Ferrous Sulfate	C	Oral	325 Mg, Bid		Not Reported
	Albuterol Hfa	C		2.5 Mg Nebulized		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18183201	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0491291		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported
	Ascorbic Acid			C		500 Mg, Bid		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported

	Ceftriaxone	C	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg		Not Reported
	Lantus	C	Subcutaneous	10 Units Bid		Not Reported
	Lantus	C	Subcutaneous	15 Units Bid		Not Reported
	Lantus	C	Subcutaneous	10 Units Bid		Not Reported
	Multivitamins;Minerals	C	Oral	1 Tab		Not Reported
	Pantoprazole	C	Oral	40 Mg, Qd		Not Reported
	Thiamine	C	Oral	100 Mg, Bid		Not Reported
	Zinc Sulphate	C	Oral	220 Mg, Qd		Not Reported
	Heparin	C		Unk		Not Reported
	Decadron A	C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Insulin	C				Not Reported
	Glipizide	C		10 Mg, Qd		Not Reported
	Metformin [Metformin Hydrochloride]	C		1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18208413	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0492291		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Doxycycline			C	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg		Not Reported

Fentanyl	C	Intravenous (not otherwise specified)	Unk		Not Reported
Heparin	C	Intravenous drip	Unk		Not Reported
Insulin Regular	C	Intravenous (not otherwise specified)	Unk		Not Reported
Norepinephrine	C				Not Reported
Oxycodone	C				Not Reported
Propofol	C				Not Reported
Rocuronium	C				Not Reported
Vasopressin	C				Not Reported
Nimbex	C				Not Reported
Midazolam	C				Not Reported
Zosyn	C				Not Reported
Cefepime	C				Not Reported
Piperacillin / Tazobactam	C	Intravenous (not otherwise specified)	3.375 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262663	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262667	DIRECT	Y	DE			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palliative Care	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262680	DIRECT	Y	HO			24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Therapy Interrupted	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:One Time Only;		Gilead
	Acetaminophen	C				Not Reported
	Dexamethasone	C				Not Reported
	Diphenhydramine	C				Not Reported
	Enoxaparin	C				Not Reported
	Fluticasone/Vilanterol	C				Not Reported
	Folic Acid	C				Not Reported
	Iopamidol 76%	C				Not Reported
	Biok Plus	C				Not Reported
	Morphine	C				Not Reported
	Mvi	C				Not Reported
	Ondansetron	C				Not Reported
	Oxycodone	C				Not Reported
	Piperacillin/Tazobactam	C				Not Reported
	Valacyclovir	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262747	DIRECT	Y	DE			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; General Physical Health Deterioration	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262776	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypokalaemia; Hypotension	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262790	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Hepatic Enzyme Increased; Hepatic Function Abnormal	Remdesivir	S	Intravenous (not otherwise specified)		Gilead
	Acetaminophen 650 Mg	C			Not Reported
	Hydrocodone/Acetaminophen 5/325 Mg	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262795	DIRECT	Y	OT			94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus		4 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262846	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Albuterol Hfa 2 Puff Inhaled 4x/Day			C				Not Reported
	Amiodarone 200 Mg Po Daily			C				Not Reported
	Calcium Gluconate 1g Iv X1			C				Not Reported
	Continuous Infusion Rocuronium			C				Not Reported
	Docusate 50 Mg Po Bid			C				Not Reported
	Heparin 5000 Units Subq Q8h			C				Not Reported
	Lidocaine 4% Topical Patch Daily			C				Not Reported
	Levothyroxine 100 Mcg Daily			C				Not Reported
	Continuous Infusion Vasopressin			C				Not Reported
	Midazolam Continuous Infusion			C				Not Reported
	Protonix 40 Mg Iv Q12h			C				Not Reported
	Dulera 2 Puff Bid			C				Not Reported
	Miralax 17g Bid			C				Not Reported
	Pyridostigmine 120 Mg Po 3x/Day			C				Not Reported
	Sodium Bicarb 650 Mg Bid			C				Not Reported
	Lokelma 10 G Po Daily			C				Not Reported
	Artificial Tears Q4h			C				Not Reported

		Crrt Bag			C					Not Reported
		Inhaled Flolan			C					Not Reported
		Fentanyl Continuous Infusion			C					Not Reported
		Norepinephrine Continuous Infusion			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18262851	DIRECT	Y	DE			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Hospice Care	Remdesivir			S				Gilead
	Lidocaine Patient 4% Daily			C				Not Reported
	Lorazepam 1 Mg Q4h Iv			C				Not Reported
	Lorazepam 2 Mg Iv X1			C				Not Reported
	Nystatin 100,000 Units Topically Bid			C				Not Reported
	Hydromorphone Pca			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263031	DIRECT	Y	LT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263142	DIRECT	Y	OT			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous bolus			Gilead
	Ascorbic Acid 500 Mg Po Q8h			C				Not Reported
	Aspirin 81 Mg Po Daily			C				Not Reported
	Enoxaparin 40 Mg Sc Daily			C				Not Reported
	Famotidine 20 Mg Po Bid			C				Not Reported
	Combivent 1 Puff Q6h			C				Not Reported
	Losartan 50 Mg Po Daily			C				Not Reported
	Melatonin 6 Mg Po Daily			C				Not Reported

	Methylprednisolone 40 Mg Iv Tid			C						Not Reported
	Zinc Sulfate 220 Mg Po Bid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263150	DIRECT	Y	DE			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Condition Aggravated; Hypoxia; Oliguria	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263233	DIRECT	Y	DE			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; General Physical Health Deterioration; Respiratory Distress	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263237	DIRECT	Y				53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Dispensing Error; Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263250	DIRECT	Y	OT			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

	Remdesivir			S	Intravenous bolus					Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263267	DIRECT	Y	OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263371	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Injury	Remdesivir			S				Gilead
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263375	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Loratadine			C				Not Reported
	Omeprazole			C				Not Reported
	Sildenafil			C				Not Reported
	Enoxaparin			C				Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263404	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263432	DIRECT	Y	DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Remdesivir			S	Intravenous drip			Gilead
	Haloperidol			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18263434	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Tocilizumab			C				Not Reported
	Tocilizumab			C				Not Reported
	Aspirin			C				Not Reported
	Vitamin D3			C				Not Reported
	Dexamethasone			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported

		Furosemide			C						Not Reported
		Iopamidol			C						Not Reported
		Iopamidol			C						Not Reported
		Levaquin			C						Not Reported
		Zyvox			C						Not Reported
		Lorazepam			C						Not Reported
		Merrem			C						Not Reported
		Merrem			C						Not Reported
		Solu-Medrol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18264184	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0494815		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Sodium Chloride			C				Not Reported
	Tylenol			C				Not Reported
	Miralax			C				Not Reported
	Refresh-Tears			C				Not Reported
	Norvasc			C				Not Reported
	Zithromax			C				Not Reported
	Rocephin [Ceftriaxone]			C				Not Reported
	Lisinopril			C				Not Reported
	Kcl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18264579	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0494799		18 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Dexamethasone			C		6 Mg, Qd		Unknown

Enoxaparin	C	40 Mg, Qd	Not Reported
Lorazepam	C	1 Mg, Once	Not Reported
Melatonin	C	3 Mg, Qd	Not Reported
Acetaminophen	C	650 Mg, Prn	Not Reported
Ondasetron [Ondansetron]	C	4 Mg, Qid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18266497	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Enoxaparin 40mg Sc Daily			C				Not Reported
	Lisinopril 10mg Bid			C				Not Reported
	Pravastatin 40mg Hs			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18266499	DIRECT	Y	OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pulse Absent; Torsade De Pointes; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:1x Only;		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Brimonidine			C				Not Reported
	Calcitrol			C				Not Reported
	Carvedilol			C				Not Reported
	Dexamethason			C				Not Reported
	Fluoxetine			C				Not Reported
	Isosorbide			C				Not Reported
	Latanoprost			C				Not Reported
	Pregabalin			C				Not Reported
	Sevlamer Carbonate			C				Not Reported
	Torsemide			C				Not Reported

	Tramadol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18266500	DIRECT	Y				24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18266501	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Bradycardia; Condition Aggravated; Drug Intolerance; Hypotension; Hypoxia; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18266503	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension; Hypoxia; Palliative Care	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18266504	DIRECT	Y	DS, HO			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Agitation; Drug Interaction; Drug Level Increased; Mental Status Changes; Restlessness; Tremor; Unresponsive To Stimuli	Remdesivir			S	Intravenous drip		4 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18266505	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18266506	DIRECT	Y	OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Albumin			C				Not Reported
	Asa			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported
	Famotidine			C				Not Reported
	Metoprolol			C				Not Reported
	Kcl			C				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2020	18267039	DIRECT	Y	DE			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Therapy Non-Responder	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17857103	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0468777		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Covid-19; Hypokalaemia; Hypomagnesaemia; Hypotension; Paralysis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albumin			C				Not Reported
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	6 Puff Q6 Hr		Not Reported
	Bumetanide			C	Intravenous (not otherwise specified)	0.5 Mg/Hr		Not Reported
	Caffeine Citrate			C				Not Reported
	Chlorothiazide			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C		20 Mg, Po Or Iv		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	20-60 Mg Prn		Not Reported
	Gabapentin			C	Oral	600 Mg, Q8h		Not Reported
	Insulin Glargine			C	Subcutaneous	12 Units Q12 Hr		Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C	Subcutaneous	1-10 Units Prn		Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Regular Hm			C	Subcutaneous	5 Units 4x Per Day		Not Reported
	Lactulose			C	Oral	20 G 4x Per Day		Not Reported
	Magnesium Sulfate			C	Intravenous (not otherwise specified)	1 G		Not Reported
	Methylprednisolone			C				Not Reported
	Metolazone			C	Oral	10 Mg, Bid		Not Reported
	Midazolam			C				Not Reported
	Midodrine			C	Oral	15-20 Mg 3-4 X Per Day		Not Reported
	Oxycodone			C	Oral	10 Mg, Q6h		Not Reported

Piperacillin/Tazobactam	C	Intravenous (not otherwise specified)	4.5 G, Q6h	Not Reported
Potassium Chloride	C	Intravenous (not otherwise specified)	10-20 Meq Prn	Not Reported
Quetiapine	C	Oral	50 Mg Q8-12 Hr	Not Reported
Quetiapine	C			Not Reported
Rocuronium	C		0-12 Mcg/Kg/Min, Titrated To Tof 2/4	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	Dosed By Level, Received 2 Doses	Not Reported
Dexmedetomidine	C	Intravenous (not otherwise specified)	1.5-2 Mcg/Kg/Hr	Not Reported
Epoprostenol	C	Respiratory (inhalation)	0.2 Mg/Hr	Not Reported
Heparin	C	Intravenous (not otherwise specified)	Titrated To Anti-Xa Or Aptt Goal	Not Reported
Hydromorphone	C	Intravenous (not otherwise specified)	0-5 Mg/Hr	Not Reported
Hydromorphone	C			Not Reported
Ketamine	C	Intravenous (not otherwise specified)	45-50 Mcg/Kg/Min	Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)	0-20 Mcg/Min, Titrated To Map >65	Not Reported
Norepinephrine	C			Not Reported
Propofol	C			Not Reported
Vasopressin	C	Intravenous (not otherwise specified)	0.04 Units/Min	Not Reported
Vasopressin	C			Not Reported
Acetaminophen	C	Oral	650 Mg, Q6h Prn	Not Reported
Acetaminophen	C			Not Reported
Fentanyl	C			Not Reported
Calcium Gluconate	C	Intravenous (not otherwise specified)	50 Ml/Hr	Not Reported
Alteplase	C	Intravenous bolus	5 Mg Bolus, Then 2 Mg/Hr	Not Reported
Cisatracurium	C	Intravenous (not	0.5-3 Mcg/Kg/Min	Not Reported

				otherwise specified)		
	Meropenem		C	Intravenous (not otherwise specified)	500 Mg, Q8h	Not Reported
	Nimbex [Nimesulide]		C			Not Reported
	Seroquel		C			Not Reported
	Zosyn		C			Not Reported
	Vecuronium		C			Not Reported
	Levophed		C			Not Reported
	Ceftriaxone		C			Not Reported
	Azithromycin		C			Not Reported
	Dilaudid Hp		C			Not Reported
	Precedex		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	17919795	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473915		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin (E.C.)			C	Oral	81 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Once		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	250 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg Q12h		Not Reported
	Enoxaparin			C	Subcutaneous	80 Mg Q12h		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	40 Mg 2-3 Per Day		Not Reported
	Guaifenesin			C	Oral	600 Mg Q12h		Not Reported
	Senna And Docusate Sodium			C	Oral	1 Tab Qhs		Not Reported

	Benzonatate	C	Oral	100 Mg, Tid, Prn	Not Reported
	Melatonin	C	Oral	3 Mg, Qhs, Prn	Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	600 Mg, Once	Not Reported
	Acetaminophen	C	Oral	1000 Mg, Q6h, Prn	Not Reported
	Acetaminophen	C			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	40 Mg, Bid	Not Reported
	Methylprednisolone	C			Not Reported
	Nitric Oxide	C	Respiratory (inhalation)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18084211	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0486110		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once (In 250 Ml Ns)		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd (In 250 Ml Ns)		Gilead
	Acetaminophen			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Levophed			C		Unk		Not Reported
	Tocilizumab			C		Unk Unk, Once		Not Reported
	Plasma			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Zithromax			C		Unk, In Ns		Not Reported
	Rocephin			C		Unk		Not Reported
	Rocephin			C		Unk		Not Reported
	Oxygen			C				Not Reported
	Maxipime			C		Unk		Not Reported
	Maxipime			C		Unk		Not Reported

Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported
Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported
Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported
Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported
Albuterol [Salbutamol]	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Duoneb	C	Unk	Not Reported
Duoneb	C	Unk	Not Reported
Insulin Nph [Insulin Isophane Bovine]	C	Unk	Not Reported
Motrin [Ibuprofen]	C	Unk	Not Reported
Beneprotein	C	Unk	Not Reported
Precedex	C	Unk, In Ns	Not Reported
Precedex	C	Unk, In Ns	Not Reported
Midazolam Hcl	C	Unk	Not Reported
Midazolam Hcl	C	Unk	Not Reported
Insulin Regular [Insulin Bovine]	C	Unk	Not Reported
Acyclovir Sodium	C	Unk	Not Reported
Zofran [Ondansetron]	C	Unk	Not Reported
Vancocin	C	Unk, In Ns	Not Reported
Protonix [Omeprazole]	C	Unk	Not Reported
Lasix [Furosemide]	C	Unk	Not Reported
Sublimaze [Fentanyl Citrate]	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Phenylephrine	C	Unk	Not Reported
Insulin Lispro	C	Unk	Not Reported
Pepcid [Famotidine]	C	Unk	Not Reported

	Bactroban Ointment	C	Unk	Not Reported
	Definity	C	Unk	Not Reported
	Calcium Gluconate	C	Unk	Not Reported
	Heparin Sodium	C	Unk	Not Reported
	Etomidate	C	Unk	Not Reported
	Zemuron	C	Unk	Not Reported
	Quelicin	C	Unk	Not Reported
	Calcium Chloride	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18100690	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487549		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergic Oedema; Hypersensitivity; Urticaria	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C	Oral	6 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	30 Mg		Not Reported
	Potassium Chloride			C		20 Meq		Not Reported
	Insulin Lispro			C	Subcutaneous	1-2 Units		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18168926	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0490653		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Abnormal; Aspartate Aminotransferase Increased; Atrial Fibrillation; Blood Alkaline	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead

Phosphatase Increased; Cardiac Arrest; Cytokine Storm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18171710	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0490941		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tylenol			C		2 Dosage Form, 650mg X 2, Q4hr, Prn		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18218817	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0492699		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Insulin			C		Unk		Not Reported
	Piperacillin & Tazobactam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18264811	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2020-047282		57 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Azithromycin Film Coated Tablet			S	Unknown	500 Milligram, Once A Day		Aurobindo

500 Mg				(1 Dd 1 Tablet)	
Codeine		S	Unknown	1 Dosage Form, 3 Times A Day (2 Dd 1 Tablet En Om 22:00 2 Tabletten)	Not Reported
Remdesivir		S	Unknown	100 Milligram, Once A Day (1 Dd 100 Mg)	Not Reported
Clexane		C	Unknown	1 Dosage Form (Injectievloeistof, 10.000 Ie/Ml (Eenheden Per Milliliter))	Not Reported
Oxazepam		C	Unknown	10 Milligram	Not Reported
Pantoprazol		C	Unknown	40 Milligram	Not Reported
Dexamethason		C	Unknown	1 Dosage Form	Not Reported
Ceftriaxon		C	Unknown	2000 Milligram	Not Reported
Loperamide		C	Unknown	2 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267220	DIRECT	Y	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Shortened	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:1x Only;		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Calcitrol			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin Subcutaneous			C				Not Reported
	Hydrocortisone-Pramoxine			C				Not Reported
	Lisinopril			C				Not Reported
	Pantoprazole			C				Not Reported
	Torsemide			C				Not Reported
	Potassium Bicarb-Citric Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267225	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Not Reported
	Piperacillin Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267229	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time Only;		Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Iopamidol 76%			C				Not Reported
	Fluticasone/Vilanterol			C				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267236	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Hepatitis; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:1st Dose, Then 100;		Gilead
	Etomidate			C				Not Reported
	Rocuronium Ijection			C				Not Reported
	Propofol			C				Not Reported
	Solu-Medrol			C				Not Reported
	Tylenol			C				Not Reported
	Lorazepam			C				Not Reported
	Omnipaque			C				Not Reported
	Pantoprazole			C				Not Reported
	Zithromax			C				Not Reported
	Ceftriaxone			C				Not Reported

			Fentanyl			C				Not Reported
			Midazolam			C				Not Reported
			Heparin			C				Not Reported
			Cisatracurium			C				Not Reported
			Levophed			C				Not Reported
			Insulin			C				Not Reported
			Iodixal			C				Not Reported
			Calium Gluconate			C				Not Reported
			Dexmedetomidine			C				Not Reported
			Oxycodone			C				Not Reported
			Guaifenesin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267241	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albumin			C				Not Reported
	Amiodarone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Fludricortisone			C				Not Reported
	Furosemide			C				Not Reported
	Haloperidol			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Iopamidol 76%			C				Not Reported
	Biok Plus			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Metoclopramide			C				Not Reported
	Midodrine			C				Not Reported
	Mvi			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Potassium Chloride			C				Not Reported
	Potassium Phosphate			C				Not Reported
	Remdesivir			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267245	DIRECT	Y	HO			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir Lyophilized Powder	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267250	DIRECT	Y	OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time Only;		Gilead
	Acetaminophen			C				Not Reported
	Chlorhexidine 0.12%			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Midazolam			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Remdesivir			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267275	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir Lyophilized Powder			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267292	DIRECT	Y				65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transcription Medication Error; Wrong Patient Received Product; Wrong Schedule	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267332	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Wrong Patient Received Product	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18267374	DIRECT	Y				71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dialysis	Remdesivir			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18268103	DIRECT	Y	OT			91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous drip			Gilead
	Ceftazidime			C				Not Reported
	Heparin Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18268241	DIRECT	Y	DE			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Disorder	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18271659	DIRECT	Y	DE, OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Arrest; Disseminated Intravascular Coagulation; Fungal Infection; Liver Function Test Increased; Shock; Ventricular Tachycardia	Remdesivir			S				Gilead
	Amiodarone			C				Not Reported
	Lidocaine			C				Not Reported
	Amphotericin B			C				Not Reported
	Norepinephrine			C				Not Reported
	Vancomycin			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18271665	DIRECT	Y	HO, OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 6 Mg			C				Not Reported
	Ventolin Hfa			C				Not Reported
	Eliquis 5 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18271670	DIRECT	Y				68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18271707	DIRECT	Y	DE			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Pressure Systolic Decreased; Cardiac Arrest; Hypoxia; Liver Function Test Increased; Pyrexia; Sars-Cov-2 Test Positive; Serum Ferritin Increased; Tachycardia	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2020	18304896	DIRECT					80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Off Label Use; Pleural Effusion; Sepsis; Superinfection	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18183213	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0491560		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Unknown	Unk		Gilead
	Furosemide			C				Not Reported
	Chlorothiazide			C				Not Reported
	Vancomycin			C				Not Reported
	Sodium Chloride			C		500 Ml Iv Bolus		Not Reported

Zaroxolyn	C			Not Reported
Acetaminofen	C			Not Reported
Enoxaparin	C		100 Mg	Not Reported
Enoxaparin	C		40 Mg	Not Reported
Promethazine H	C	Topical		Not Reported
Zofran	C			Not Reported
Pantoprazole	C			Not Reported
Aspirin (E.C.)	C			Not Reported
Magnesium Sulfate	C			Not Reported
Melatonin	C			Not Reported
Hydroxyzine Hcl	C			Not Reported
Mupirocin	C			Not Reported
Famotidine	C			Not Reported
Dexamethasone	C			Not Reported
Cefepime Hcl	C			Not Reported
Perflutren	C			Not Reported
Epinephrine	C			Not Reported
Rocuronium Bromide	C			Not Reported
Morphine Sulf	C			Not Reported
Sodium Bicarbonate	C			Not Reported
Polyethylene Glycol	C			Not Reported
Midazolam Hydrochloride	C			Not Reported
Cisatracurium	C			Not Reported
Solu-Cortef	C			Not Reported
Angiotensin Ii	C			Not Reported
Heparin Sodium	C			Not Reported
Tobramycin	C			Not Reported
Prismasate	C			Not Reported
Micafungin Sodium	C			Not Reported
Fentanyl	C			Not Reported
Vasopressin	C			Not Reported
Ketamine	C			Not Reported
Precedex	C			Not Reported
Norepinephrine	C			Not Reported
Lactated Ringer'S	C			Not Reported
Metronidazole	C			Not Reported
Plasma-Lyte A	C			Not Reported
Midodrine	C			Not Reported
Ceftriaxone Sodium	C			Not Reported
Insulin Lispro	C			Not Reported
Glucagon	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18238254	EXPEDITED (15-DAY)		DS, LT, OT	US-ROCHE-2671246		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Sepsis; Gastric Ulcer Perforation; Pulmonary Fibrosis; Septic Shock; Shock	Tocilizumab			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose Of Tocilizumab: 11/Jul/2020 At 23:34 (100 Ml)		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Rdv Loading Dose On Day 1, And A Once-Daily Maintenance Dose Of Remdesivir From Days 2-10 Date Of Mo		Not Reported
	Decadron			C				Not Reported
	Lovenox			C				Not Reported
	Lovenox			C				Not Reported
	Tessalon			C				Not Reported
	Imodium			C				Not Reported
	Morphine			C				Not Reported
	Morphine			C				Not Reported
	Oxycodone			C				Not Reported
	Oxycodone			C				Not Reported
	Ocean			C		2 Spray		Not Reported
	Flexeril			C				Not Reported
	Oxygen			C		2 Others		Not Reported
	Zosyn			C				Not Reported
	Zosyn			C				Not Reported
	Fluconazole			C				Not Reported
	Albumin			C				Not Reported
	Ancef (United States)			C				Not Reported
	Cipro			C				Not Reported
	Diflucan			C				Not Reported
	Arixtra			C				Not Reported
	Flagyl			C				Not Reported
	Levophed			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18271658	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-047606		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Exposure During Pregnancy; Inferior Vena Cava Syndrome; Off Label Use; Septic Shock	Dexamethasone			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272077	DIRECT	Y	OT			14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272176	DIRECT	Y	HO			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272592	DIRECT	Y				82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytosis	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272618	DIRECT	Y	HO			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Liver Injury	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272641	DIRECT	Y				46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272646	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272650	DIRECT	Y	RI			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melaena	Enoxaparin (Enoxaparin 40mg/0.4ml Inj)			S	Subcutaneous			Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272655	DIRECT	Y				80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272668	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; International Normalised Ratio Abnormal; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272679	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272680	DIRECT	Y				77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)				Not Reported
	Ceftriaxone (Ceftriaxone Na 1gm/Vil Inj)			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272682	DIRECT	Y				86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272730	DIRECT	Y				27 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272757	DIRECT	Y				55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272847	DIRECT	Y	OT			18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir	S	Intravenous bolus		Gilead
	Amoxicillin 500 Mg Po Q8h	C			Not Reported
	Ascorbic Acid 500 Mg Po Tid	C			Not Reported
	Aspirin 81 Mg Po Daily	C			Not Reported
	Cholecalciferol 2000 Units Po Daily	C			Not Reported
	Docusate 100 Mg Po Daily	C			Not Reported
	Enoxaparin 40 Mg Sc Daily	C			Not Reported
	Famotidine 20 Mg Po Bid	C			Not Reported
	Methylprednisolone 40 Mg Iv Q6h	C			Not Reported
	Prenatal Vitamin 1 Po Daily	C			Not Reported
	Zinc Sulfate 220 Mg Po Bid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18272854	DIRECT	Y	OT			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273028	DIRECT	Y				84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir (Veklury)			S	Intravenous bolus		2 DAY	Gilead
	Amlodipine			C				Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin/Codeine			C				Not Reported

		Guaifenesin Xr			C					Not Reported
		Insulin Lispro			C					Not Reported
		Melantonin			C					Not Reported
		Levothyroxine			C					Not Reported
		Tamsulosin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273043	DIRECT	Y				51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 6mg Daily			C				Not Reported
	Olanzapine 2.5mg Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273103	DIRECT	Y	RI			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Above Therapeutic; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273338	DIRECT	Y	HO			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18273429	DIRECT	Y	LT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Hypoxia; Liver Function Test Increased; Sinus Arrest	Remdesivir For Injection 100 Mg/20 Ml	Y	S	Intravenous (not otherwise specified)		Gilead
	Acetaminophen 650 Mg Po Prn		C			Not Reported
	Atorvastatin 80 Mg Po Qpm		C			Not Reported
	Ceftriaxone 1 G Iv Q24h		C			Not Reported
	Dexamethasone 6 Mg Iv Q24h		C			Not Reported
	Enoxaparin 70 Mg Sc Q12h		C			Not Reported
	Ergocalciferol 50,000 Unit Q7d		C			Not Reported
	Guaifenesin 10 Ml Po Q6h Prn		C			Not Reported
	Ipratropium/Albuterol Nebulizer 3 Ml Qid Prn		C			Not Reported
	Latanoprost 0.005% Opth 1 Drop Ou Qhs		C			Not Reported
	Ondansetron 4 Mg Iv Q6h Prn		C			Not Reported
	Zinc Sulfate 220 Mg Po Q24h		C			Not Reported
	Azithromycin 500 Mg Iv/Po Daily		C			Not Reported
	Famotidine 20 Mg Iv/Po Bid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18275695	EXPEDITED (15-DAY)			US-GILEAD-2020-0495170		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18276789	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus	Other Frequency:One Time;	1 DAY	Gilead
	Propofol			C				Not Reported
	Dexamethasone 10mg Iv One Time			C				Not Reported
	Dexmedetomidine			C				Not Reported

		Enoxaparin Sq Q12h		C					Not Reported
		Famotidine 20mg Iv Q12h		C					Not Reported
		Fentanyl Iv Drip		C					Not Reported
		Ketamine		C					Not Reported
		Lactated Ringers		C					Not Reported
		Methylprednisolone Sodium Succinate		C					Not Reported
		Midazolam Iv		C					Not Reported
		Norepinephrine		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18276793	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoptysis; Incorrect Dose Administered; Liver Function Test Increased	Remdesivir Eua			S	Intravenous (not otherwise specified)			Gilead
	Dexamathasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Benzonatate			C				Not Reported
	Prednisone			C				Not Reported
	Fluticasone			C				Not Reported
	Levothyroxine			C				Not Reported
	Losartan			C				Not Reported
	Metoprolol			C				Not Reported
	Montelukast			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18276987	DIRECT	Y	DE			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Azotaemia; Bilevel Positive Airway Pressure; Condition Aggravated; Haemodialysis; Sars-Cov-2 Antibody Test Positive	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18281724	DIRECT		OT			35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir 100mg (2 Vials)	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg (1 Vial)			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18311303	DIRECT					60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2020	18311845	DIRECT					70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Device Use Issue; Liver Injury; Product Use Issue; Respiratory Disorder	Lopinavir			S				Not Reported
	Ritonavir			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	17971034	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0477731		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury;	Remdesivir			S	Intravenous (not	200 Mg, Qd		Gilead

Bradycardia; Cardiac Arrest; Electrocardiogram Qrs Complex Prolonged; Heart Rate Decreased; Hepatic Enzyme Increased; Hypotension; Liver Disorder; Pulseless Electrical Activity; Renal Tubular Necrosis; Respiratory Disorder			otherwise specified)		
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Amiodarone	S	Intravenous (not otherwise specified)	0.5 Mg, Q1minute	Not Reported
	Ivermectin	C		Unk	Not Reported
	Tocilizumab	C		Unk	Not Reported
	Plasma	C			Not Reported
	Calcium Gluconate	C			Not Reported
	Ceftriaxone	C			Not Reported
	Clinimix E	C			Not Reported
	Norepinephrine	C			Not Reported
	Phenylephrine	C			Not Reported
	Propofol	C			Not Reported
	Sodium Bicarbonate	C			Not Reported
	Vasopressin	C			Not Reported
	Acetaminophen	C			Not Reported
	Albuterol Hfa	C			Not Reported
	Ascorbic	C			Not Reported
	Chlorhexidine	C			Not Reported
	Cholecalciferol	C			Not Reported
	Enoxaparin	C			Not Reported
	Epinephrine	C			Not Reported
	Etomidate	C			Not Reported
	Famotidine	C			Not Reported
	Heparin	C			Not Reported
	Solu-Medrol	C			Not Reported
	Metoprolol	C			Not Reported
	Petrolatum/Mineral Oil	C			Not Reported
	Ondansetron	C			Not Reported
	Rocuronium	C			Not Reported
	Kayexalate	C			Not Reported
	Zinc Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18083224	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0485103		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Blood Urea Increased; Sepsis	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once	Gilead
	Remdesivir	S			Gilead
	Atorvastatin	C	Oral	40 Mg	Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Pitressin [Vasopressin]	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Propofol	C		Unk	Not Reported
	Fentanyl Citrate	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Solumedrol	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Rocephine	C	Intravenous (not otherwise specified)	2 G	Not Reported
	Lovenox Hp	C	Subcutaneous	30 Mg	Not Reported
	Famotidine	C	Intravenous (not otherwise specified)	20 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18276250	EXPEDITED (15-DAY)			US-GILEAD-2020-0495320		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18277616	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Remdesivir			S				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18277773	DIRECT	Y	HO			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Eliquis			C				Not Reported
	Lovenox			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18277903	DIRECT	Y	HO			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Regular			C				Not Reported
	Lisinopril			C				Not Reported
	Lorazepam			C				Not Reported
	Metoprolol Tartarate			C				Not Reported
	Ondansteron			C				Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18277938	DIRECT		DE			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Condition Aggravated; Respiratory Disorder	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18277943	DIRECT		DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia;	Remdesivir			S				Not Reported
Therapy Non-Responder	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278316	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus			Unknown
	Cisatracurium			C				Not Reported
	Fentanyl, Versed, Propofol			C				Not Reported
	Lovenox			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Cefepime			C				Not Reported
	Pepcid, Docusate, Senna, Miralax			C				Not Reported
	Peridex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278320	DIRECT	Y				40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Robitussin Dm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278820	EXPEDITED (15-DAY)			US-GILEAD-2020-0495314		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18278831	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1079103		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Bid,Started On Hospital Day 6 As A Bridge To Compassionate Use Of Remdesivir; 2 Doses		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Mylan
	Tocilizumab			S	Unknown	800 Mg, Qd Given On Hospital Day 7 And 8		Mylan
	Remdesivir			S	Unknown	Off Label Use Of Remdesivir Started On Hospital Day 10; 100 Mg Daily For Five Doses		Mylan
	Vincristine			C	Unknown	Unk		Mylan
	Irinotecan			C	Unknown	Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18279567	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0495142		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
	Enoxaparin			C	Subcutaneous	40 Mg, Qd		Not Reported
	Lisinopril			C		10 Mg, Bid		Not Reported
	Pravastatin			C		40 Mg Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18280374	EXPEDITED (15-DAY)			US-GILEAD-2020-0495306		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18281385	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18281686	DIRECT	Y	HO, OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir 100mg/Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg/Vial	Y		S	Intravenous (not otherwise specified)	Route: Iv X 3 Doses		Gilead

	Ceftriaxone	C	Not Reported
	Azithromycin	C	Not Reported
	Iodixanol (Visipaque)	C	Not Reported
	Dexamethasone	C	Not Reported
	Citalopram	C	Not Reported
	Lamotrigine	C	Not Reported
	Metoprolol Succinate	C	Not Reported
	Vitamin C	C	Not Reported
	Zinc Gluconate	C	Not Reported
	Guaifenesin Er	C	Not Reported
	Albuterol Mdi	C	Not Reported
	Exoxaparin	C	Not Reported
	Apap	C	Not Reported
	Lorazepam	C	Not Reported
	Ondansetron Odt	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18281743	DIRECT	Y	OT			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Bundle Branch Block Right	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18282169	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Critical Illness	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18282192	DIRECT	Y	DE			92 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pneumonia Bacterial;	Remdesivir			S	Intravenous bolus			Gilead

Respiratory Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2020	18282226	DIRECT	Y	HO			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18281506	DIRECT	Y	OT			28 YR	Female	GUM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Furosemide			C				Not Reported
	Pantoprazole			C				Not Reported
	Senna/Docusate			C				Not Reported
	Thiamine			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Gentamicin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18281749	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18281812	DIRECT	Y	OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282323	DIRECT	Y				32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S			3 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282369	EXPEDITED (15-DAY)			US-GILEAD-2020-0495319		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration	Remdesivir			S	Unknown			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282386	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Oral			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282418	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S			4 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282603	DIRECT	Y	DE			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Cardiac Arrest; Multiple Organ Dysfunction Syndrome	Remdesivir	Y		S	Intravenous drip			Gilead
	Tocilizumab	Y		S	Intravenous drip	Other Frequency:Once;		Roche
	Vancomycin			C				Not Reported
	Ceftrixaone			C				Not Reported
	Furosemide			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282608	DIRECT	Y	DE			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospice Care	Remdesivir	Y		S	Intravenous drip			Gilead
	Vancomycin			C				Not Reported
	Ceftrixaone			C				Not Reported
	Furosemide			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282613	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus		5 DAY	Gilead
	Actemra			C				Not Reported
	Dexamethasone			C				Not Reported
	Bumex			C				Not Reported
	Furosemide			C				Not Reported
	Protonix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282841	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Heart Rate Decreased; Hypoxia	Remdesivir	Y		S	Intravenous drip			Gilead
	Vancomycin			C				Not Reported
	Ceftrixaone			C				Not Reported
	Iv Contrast			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282873	DIRECT	Y	DE			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodynamic Instability	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282877	DIRECT	Y	DE, OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bradycardia; Hypotension	Remdesivir	Y		S	Intravenous drip			Gilead
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Norepinephrine			C				Not Reported
	Dobutamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18282893	DIRECT	Y	HO			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18283020	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Septic Shock	Remdesivir	Y		S	Intravenous drip			Not Reported
	Vancomycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Metolazone			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287560	DIRECT	Y	DE			72 YR	Female	AFG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Cardiac Arrest; Haemodialysis; Hypertension; Renal Tubular Necrosis; Sepsis; Septic Shock	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Azithromycin 500 Mg Iv X 1, Then 250 Mg Po Once Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Dailly			C				Not Reported
	Cefepime 1 Gm Iv Q6hr Renally Dosed Through Course Of Therapy			C				Not Reported
	Vancomycin			C				Not Reported
	Metronidazole 500 Mg Po Q8hr			C				Not Reported
	Heparin Drip			C				Not Reported

		Famotodine 20 Mg Iv/Po Bid			C						Not Reported
		Enoxaparin 40 Mg Sq Q 24hr			C						Not Reported
		Hydrocortisone 50 Mg Iv Q8hr			C						Not Reported
		Melatonin 9 Mg Po Once Daily			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287565	DIRECT	Y	OT			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Albumin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Famotidine			C				Not Reported
	Heparin Sc			C				Not Reported
	Insulin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Ofirmev			C				Not Reported
	Labetalol			C				Not Reported
	Precedex			C				Not Reported
	Heparin Drip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287569	DIRECT	Y	OT			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Then 100mg Daily;		Gilead
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Furosemide			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Quetiapine Fumarate			C				Not Reported
	Diltiazem			C				Not Reported
	Heparin			C				Not Reported
	Propofol			C				Not Reported

		Albuterol			C					Not Reported
		Lidocaine Hcl 1%			C					Not Reported
		Regular Insulin			C					Not Reported
		Levaquin			C					Not Reported
		Vitamin D3			C					Not Reported
		Metoprolol			C					Not Reported
		Benzonatate			C					Not Reported
		Vitamin C			C					Not Reported
		Zinc Sulfate			C					Not Reported
		Enoxaparin			C					Not Reported
		Famotidine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287573	DIRECT	Y	DE			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Acute Respiratory Failure; Anaemia; Cardiac Arrest; Hypoxia; Malnutrition; Metabolic Disorder; Multiple Organ Dysfunction Syndrome; Pneumothorax; Renal Tubular Necrosis; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Amiodarone Drip, Then 200 Mg Po Once Daily			C				Not Reported
	Atorvastatin 20 Mg Po Once Daily			C				Not Reported
	Ascorbic Acid 1000 Mg Po Q12h			C				Not Reported
	Aspirin 81 Mg Po Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Vitamin D3 800 Units Po Once Daily			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Enoxaparin 80 Mg Sq Q12hr			C				Not Reported
	Enoxaparin 40 Mg Sq Q 24hr			C				Not Reported
	Heparin 5,000 Units Sq Q12hr			C				Not Reported
	Lisinopril 10 Mg Po Once Daily			C				Not Reported
	Melatonin 9 Mg Po Hs			C				Not Reported
	Meropenem Iv Renally Adjusted			C				Not Reported
	Methylprednisolone 40 Mg Iv Daily			C				Not Reported
	Metoprolol Tartrate 25 Mg Po 12.5 Mg Bid			C				Not Reported
	Micafungin 100 Mg Iv Once			C				Not Reported

		Daily								
		Piperacillin/Tazo 3.375 Gm Iv Q8hr			C					Not Reported
		Vancomycin			C					Not Reported
		Zinc Sulfate 220 Mg Po Bid			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287632	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Medication Error; Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287639	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Medication Error; Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287667	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287673	DIRECT	Y	OT			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S				Not Reported
	Rosuvastatin			C				Not Reported

Aminotransferase Increased; Liver Function Test Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287964	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Reaction With Eosinophilia And Systemic Symptoms; Rash Morbilliform; Transaminases Increased	Remdesivir			S				Not Reported
	Methylprednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2020	18287981	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18287615	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Cefepime			C				Not Reported
	Epinephrine			C				Not Reported
	Folic Acid			C				Not Reported
	Heparin			C				Not Reported
	Atrovent			C				Not Reported
	Ventolin			C				Not Reported
	Flagyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Solu-Medrol			C				Not Reported
	Pantoprazole			C				Not Reported

		Vasopressin			C						Not Reported
		Thiamine			C						Not Reported
		Sodium Bicarbonate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18287643	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Traumatic Lung Injury	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18288180	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)			Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2020	18288238	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Coagulopathy; Fluid Imbalance; Hepatic Failure; Hyperkalaemia; Hypoglycaemia; Multiple Organ Dysfunction Syndrome	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)	Other Frequency:Initial X1; Frequency: Daily X 9		Gilead
	Convalescent Plasma:			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

	Pantoprazole			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	17919777	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473916		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg, Q4hr		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Once		Not Reported
	Calcium Carbonate			C	Oral	1000 Mg, Bid		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg, Qd		Not Reported
	Insulin Glargine			C	Subcutaneous	5 Units		Not Reported
	Insulin Lispro			C	Subcutaneous	1-8		Not Reported
	Maraviroc			C	Oral	300 Mg Q12h		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Mg, Bid		Not Reported
	Senna And Docusate Sodium			C	Oral	2 Tab Qhs		Not Reported
	Ergocalciferol			C	Oral	50,000 Units Weekly		Not Reported
	Guaifenesin & Codeine			C	Oral	5 Ml		Not Reported
	Guaifenesin & Codeine			C				Not Reported
	Trazodone			C	Oral	50 Mg, Qhs Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18130648	EXPEDITED (15-DAY)			US-GILEAD-2020-0489283		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Closure Issue; Product Label Issue; Product Preparation Error	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18189981	EXPEDITED (15-DAY)		HO, LT	US-GILEAD-2020-0491658		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Carvedilol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Aspart			C				Not Reported
	Multivitamins;Minerals			C				Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Potassium Chloride			C				Not Reported
	Zolpidem			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18225047	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0492934		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Atorvastatin			C	Oral	10 Mg		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G		Not Reported
	Dexamethasone			C	Intravenous (not	6 Mg		Not Reported

						otherwise specified)				
	Lisinopril			C		Oral	20 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18287926	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1080189		57 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Azithromycin			S		1 Dd 1 Tablet		Mylan
	Codeine			S		2 Dd 1 Tablet En Om 22:00 2 Tabletten		Mylan
	Remdesivir			S		1 Dd 100 Mg		Mylan
	Oxazepam			S		Tablet, 10 Mg (Milligram)		Mylan
	Dexamethason /00016001/			C		Injectievloeistof, 1 Mg/Ml (Milligram Per Milliliter)		Mylan
	Enoxaparin			C		Injectievloeistof, 10.000 Ie/Ml (Eenheden Per Milliliter)		Mylan
	Loperamide			C		Capsule, 2 Mg (Milligram)		Mylan
	Ceftriaxon			C		Oplossing Voor Infuus, 2000 Mg (Milligram)		Mylan
	Pantoprazol /01263201/			C		Maagsapresistente Tablet, 40 Mg (Milligram)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18288692	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0495769		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cefepime			C				Not Reported

	Vancomycin	C		Not Reported
	Metronidazole	C		Not Reported
	Heparin	C		Not Reported
	Famotidine	C		Not Reported
	Enoxaparin	C		Not Reported
	Hydrocortisone	C		Not Reported
	Melatonin	C		Not Reported
	Epinephrine	C		Not Reported
	Calcium Chloride	C		Not Reported
	Dextrose	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18288828	DIRECT	Y	LT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Condition Aggravated; Respiratory Failure	Remdesivir	Y		S	Intravenous drip			Gilead
	Vancomycin			C				Not Reported
	Zosyn			C				Not Reported
	Nimbex			C				Not Reported
	Fentanyl			C				Not Reported
	Levophed			C				Not Reported
	Phenylephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18288841	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18288851	DIRECT	Y				36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Tachycardia	Remdesivir			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18288853	DIRECT	Y				76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatotoxicity; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amiodarone			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Guaifenesin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Humalog Mix			C				Not Reported
	Lactobacillus Acidophilus			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Methylprednisolone Succ			C				Not Reported
	Pantoprazole			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18289303	DIRECT	N	HO			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Respiratory Failure	Remdesivir			S				Not Reported
	Anti-Sars-Cov-2 Convalescent Plasma (Ascov2cp)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18292769	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir Lyophilized Powder	S	Intravenous bolus	Other Frequency:200 Mg Once;	1 DAY		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18292847	DIRECT	Y	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Lactate Dehydrogenase Increased; Haptoglobin Decreased; Reticulocyte Count Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Given Twice;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin 81 Mg			C				Not Reported
	Budesonide Inhalation			C				Not Reported
	Ceftriaxone 1 G			C				Not Reported
	Cholecalciferol 5000 Int. Units Po			C				Not Reported
	Dexamethasone Sodium Phos.			C				Not Reported
	Doxycycline 100 Mg Iv			C				Not Reported
	Famotidine 20 Mg			C				Not Reported
	Furosemide 40 Mg X 1			C				Not Reported
	Guaifenesin 600 Mg			C				Not Reported
	Hydralazine 10 Mg Prn			C				Not Reported
	Hydrocodone/Apap Prn			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Duoneb			C				Not Reported
	Melatonin			C				Not Reported
	Methocarbamol			C				Not Reported
	Quetiapine			C				Not Reported
	Rivaroxaban			C				Not Reported
	Thiamine			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Normal Saline 500 Ml			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2020	18292928	EXPEDITED (15-DAY)		OT	GU-GILEAD-2020-0495772		28 YR	Female	GUM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Lasix [Furosemide]			C				Not Reported
	Azithromycin			C		Unk		Not Reported
	Sodium Bicarbonate			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Senna-S [Docusate Sodium; Senna Alexandrina]			C		Unk		Not Reported
	Thiamine			C		Unk		Not Reported
	Zinc Gluconate			C		Unk		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Gentamicin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18122119	EXPEDITED (15-DAY)		DE, HO, LT	BR-ROCHE-2652680		48 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Bacterial Infection; Multiple Organ Dysfunction Syndrome	Tocilizumab			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose Of Tocilizumab Prior To Sae Onset: 29/July/2020 At 19:50 Hours		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Loading Dose On Day 1, And Then A Once-Daily Maintenance Dose From Days 2-10. On 30/Jul/2020; At 15:		Not Reported
	Tazocin			C				Not Reported
	Enoxaparin			C		Prophylaxis Of Venous		Not Reported

							Thromboembolism			
		Azithromycin			C					Not Reported
		Precedex			C					Not Reported
		Dexamethasone			C					Not Reported
		Dipyrone			C					Not Reported
		Bromopride			C					Not Reported
		Tamiflu			C		Suspect Of Influenza			Not Reported
		Magnesium Sulfate			C					Not Reported
		Omeprazole			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18219715	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0492706		93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cerebrovascular Accident; Encephalopathy; Seizure; Ventricular Extrasystoles	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dorzolamide			C		2 %		Not Reported
	Donepezil			C	Oral	5 Mg		Not Reported
	Finasteride			C	Oral	5 Mg		Not Reported
	Doxazosin			C	Oral	2 Mg		Not Reported
	Dexamethasone Sodium Phosphate			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Levetiracetam			C		Unk		Not Reported
	Colecalciferol			C		800 Units		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous	40 Mg, Qd		Not Reported
	Xalatan			C		1 Drop		Not Reported
	Sodium Chloride 0.9%			C		Unk		Not Reported
	Timoptic			C		1 Drop		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18293550	DIRECT	Y	OT			19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hepatotoxicity	Remdesivir			S				Not Reported
	Tylenol			C				Not Reported
	Betamethasone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18294104	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albumin Human 25% Iv			C				Not Reported
	Amiodarone Iv			C				Not Reported
	Dexamethasone Iv			C				Not Reported
	Doxycycline Iv			C				Not Reported
	Furosemide Iv			C				Not Reported
	Pantoprazole Iv			C				Not Reported
	Pioglitazone Po			C				Not Reported
	Ascorbic Acid Po			C				Not Reported
	Cholecalciferol Po			C				Not Reported
	Zinc Po			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18294653	DIRECT	Y				68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18294972	DIRECT	Y				29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

	Remdesivir	Y		S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18294981	DIRECT	Y				72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18295319	DIRECT	Y	OT			32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir Eua			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported
	Codeine-Guaifenesin			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18295325	DIRECT	Y	DE			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18298955	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0495909		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Acute Respiratory Distress Syndrome; Anaemia; Cardiac Arrest; Malnutrition; Organ Failure; Pneumothorax; Renal Tubular Necrosis; Sepsis	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Amiodarone	C	Oral	200 Mg	Not Reported
	Atorvastatin	C	Oral	20 Mg, Qd	Not Reported
	Ascorbic Acid	C	Oral	1000 Mg, Bid	Not Reported
	Aspirin 81	C	Oral	81 Mg, Qd	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G, Qd	Not Reported
	Vitamin D3	C	Oral	800 Units	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
	Enoxaparin	C	Subcutaneous	80 Mg, Bid	Not Reported
	Enoxaparin	C	Subcutaneous	40 Mg, Qd	Not Reported
	Heparin	C	Subcutaneous	5000 Units	Not Reported
	Lisinopril	C	Oral	10 Mg, Qd	Not Reported
	Melatonin	C	Oral	9 Mg	Not Reported
	Meropenem	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported
	Metoprolol Tartrate	C	Oral	25 Mg	Not Reported
	Micafungin	C	Intravenous (not otherwise specified)	100 Mg, Qd	Not Reported
	Piperacillin / Tazobactam	C	Intravenous (not otherwise specified)	3.375 G, Q84hr	Not Reported
	Vancomycin	C		Unk	Not Reported
	Zinc Sulfate	C	Oral	220 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299315	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299324	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Throat Tightness	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Lisinopril			C				Not Reported
	Meloxicam			C				Not Reported
	Methocarbamol			C				Not Reported
	Pantoprazole			C				Not Reported
	Albuterol			C				Not Reported
	Zaleplon			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299330	DIRECT	Y	DE			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299345	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299351	DIRECT	Y	DE			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Septic Shock	Remdesivir Tocilizumab	Y		S C				Not Reported Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299359	DIRECT	Y	DE			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299368	DIRECT	Y	DE			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299374	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

Increased; Blood Creatinine Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299393	DIRECT	Y	DE			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299398	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299405	DIRECT	Y				50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Aspirin			C				Not Reported
	Azithromycin 500 Mg Iv Q24h			C				Not Reported
	Atorvastatin 40 Mg Po Qhs			C				Not Reported
	Ceftriaxone 1 Gm Iv Daily			C				Not Reported
	Enoxaparin 180 Mg Sq Q12h			C				Not Reported
	Fenofibrate 160 Mg Po Daily			C				Not Reported
	Furosemide 40 Mg Iv Bid			C				Not Reported
	Hydrochlorothiazide 12.5 Mg Po Daily			C				Not Reported
	Methylprednisolone 20 Mg Iv Q12h			C				Not Reported
	Lisinopril 20 Mg Po Daily			C				Not Reported

	Metoprolol Cr 25 Mg Po Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299411	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Allopurinol			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported
	Famotidine			C				Not Reported
	Lovastatin 5mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299417	DIRECT	Y	DE			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Lung Infiltration; Pyrexia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2020	18299578	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis; Multiple Organ Dysfunction Syndrome; Palliative Care; Sars-Cov-2 Test Positive; Septic Shock; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Amlodipine 10 Mg Po Once Daily			C				Not Reported
	Ascorbic Acid 1000 Mg Po Once			C				Not Reported

	Daily			
	Ascorbic Acid 1000 Mg Po Once Daily	C		Not Reported
	Cefepime Renally Doses	C		Not Reported
	Colchicine 0.3 Mg Po Once Daily	C		Not Reported
	Doxycycline Po Qq12hr	C		Not Reported
	Enoxaparin 40 Mg Sq Q 24hr	C		Not Reported
	Enoxaparin 120 Mg Sq Q12hrs	C		Not Reported
	Famotidine 20 Mg Iv/Po Renally Dosed	C		Not Reported
	Insulin Glargine	C		Not Reported
	Lisinopril 20 Mg Po Once Daily	C		Not Reported
	Meropenem 1 Gm Iv Q12hr	C		Not Reported
	Methyprednisolone 40 Mg Iv	C		Not Reported
	Zinc Sulfate 220 Mg Po Once Daily	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18107384	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0488611		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Doxycycline			C				Not Reported
	Zosyn			C	Intravenous (not otherwise specified)			Not Reported
	Iviglob-Ex			C		Unk		Not Reported
	Plasma			C		Unk		Not Reported
	Argatroban			C		Unk		Not Reported
	Argatroban			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18171329	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0490900		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Aspirin [Acetylsalicylic Acid]			C		81 Mg, Qd		Not Reported
	Atorvastatin			C		80 Mg, Qd		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	30 Mg, Qd		Not Reported
	Insulin Aspart			C	Subcutaneous	Sliding Scale		Not Reported
	Moxifloxacin			C	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300473	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Renal Impairment; Therapy Cessation	Remdesivir	Y		S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Cefepime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300478	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300752	DIRECT	Y	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal	Remdesivir			S	Intravenous bolus		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300767	DIRECT	Y	DE			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300857	DIRECT	Y	DE			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dyspnoea	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300978	DIRECT	Y	DE			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300980	DIRECT	Y	DE			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300981	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospice Care	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18300988	DIRECT	Y	DE			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301049	DIRECT	Y	DE			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301052	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Dyspnoea	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301055	DIRECT	Y	DE			88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301073	DIRECT	Y	DE			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301108	DIRECT	Y	DE			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18301134	DIRECT	Y	DE			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Hyporesponsive To Stimuli; Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302434	EXPEDITED (15-DAY)		OT	SE-PERRIGO-20SE013246			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombophlebitis; Transaminases Increased	Paracetamol			S	Unknown	1 G, Qid		Perrigo
	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)	200 Mg, Once		Not Reported
	Nutriflex /07393601/			S	Parenteral			Not Reported
	Cefotaxim			S	Intravenous (not otherwise specified)	1 G, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18302941	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0496065		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C				Not Reported
	Dexamethasone			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cefepime			C				Not Reported
	Colchicine			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Lisinopril			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18305354	DIRECT		OT			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Remdesivir			S	Intravenous bolus			Not Reported
	Anakinra			C				Not Reported
	Colchicine			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Losartan			C				Not Reported
	Rosuvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18305397	DIRECT	Y				45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18305408	DIRECT	Y	OT			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

		Donepezil			C					Not Reported
		Doxycycline			C					Not Reported
		Enoxaparin			C					Not Reported
		Haloperidol			C					Not Reported
		Memantine			C					Not Reported
		Sodium Chloride 0.9%			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18306575	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Atrial Fibrillation; Condition Aggravated; Dyspnoea; General Physical Health Deterioration; Respiratory Distress; Tachycardia; Tachypnoea	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2020	18311293	DIRECT		DE, HO, OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Pneumothorax; Transfusion	Veklury® (Remdesivir)			S				Not Reported
	Blood Pressure Meds			C				Not Reported
	Cholesterol			C				Not Reported
	Stomach Pills			C				Not Reported
	Nebulizer And Oxygen			C				Not Reported
	Baby Aspirin			C				Not Reported
	Tylenol			C				Not Reported
	Tums			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18034091	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483269		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Maternal Exposure During Pregnancy	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Acetaminophen	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Dexamethasone	C		Unk	Not Reported
	Dexamethasone	C		4 Doses	Not Reported
	Dexamethasone	C		2 Doses	Not Reported
	Dexamethasone	C		Unk	Not Reported
	Potassium Phosphates	C		Unk	Not Reported
	Albuterol Sulfate	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Lactated Ringers	C		Unk	Not Reported
	Sodium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Chloride	C	Nasal	Unk	Not Reported
	Promethazine	C		Unk	Not Reported
	Pepcid [Famotidine]	C		Unk	Not Reported
	Pepcid [Famotidine]	C		Unk	Not Reported

	Melatonin	C		Unk	Not Reported
	K-Dur	C		Unk	Not Reported
	K-Dur	C		Unk	Not Reported
	K-Dur	C		Unk	Not Reported
	K-Dur	C		Unk	Not Reported
	K-Dur	C		Unk	Not Reported
	Prenatal Vitamins [Minerals Nos; Vitamins Nos]	C		Unk	Not Reported
	Bactroban Ointment	C		Unk	Not Reported
	Rocephin [Ceftriaxone Sodium]	C		Unk	Not Reported
	Zithromax	C		Unk	Not Reported
	Potassium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Lasix [Furosemide]	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18152919	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0490146		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Hydralazine			C	Oral	100 Mg, Q8h		Not Reported
	Hydralazine			C	Oral	50 Mg, Q8h		Not Reported
	Hydralazine			C	Oral	20 Mg, Q6h Prn		Not Reported
	Hydralazine			C	Oral	25 Mg, Q8h		Not Reported
	Dextrose 5%			C	Intravenous (not otherwise specified)	1000 Ml Q12h3m		Not Reported
	Dextrose 5%			C	Intravenous (not otherwise specified)	1000 Ml Q12h3m		Not Reported

Pepcid [Famotidine]	C	Other	20 Mg, Qd	Not Reported
Pepcid [Famotidine]	C	Intravenous (not otherwise specified)	20 Mg, Qd	Not Reported
Pepcid [Famotidine]	C	Intravenous (not otherwise specified)	20 Mg, Qd	Not Reported
Toprol Xl	C	Oral	25 Mg, Qd	Not Reported
Cardene	C	Intravenous (not otherwise specified)	250 Ml Titrate	Not Reported
Cardene	C	Intravenous (not otherwise specified)	250 Ml Titrate	Not Reported
Cathflo	C	Intravenous (not otherwise specified)	6 Mg, Once	Not Reported
Cathflo	C	Intravenous (not otherwise specified)	2 Mg, Once	Not Reported
Combivent	C	Respiratory (inhalation)	1 Puff Q6h	Not Reported
Norvasc	C	Other	10 Mg, Qd	Not Reported
Zyprexa	C	Intravenous (not otherwise specified)	5 Mg, Once Prn	Not Reported
Miralax	C	Other	17 G, Bid	Not Reported
Lovenox [Enoxaparin Sodium]	C	Subcutaneous	40 Mg, Bid	Not Reported
Duoneb	C	Respiratory (inhalation)	3 Ml, Q6h	Not Reported
Duoneb	C	Respiratory (inhalation)	3 Ml, Q4hr	Not Reported
Lasix [Furosemide]	C	Intravenous (not otherwise specified)	20 Mg, Once	Not Reported
Lasix [Furosemide]	C	Oral	40 Mg, Once	Not Reported
Lasix [Furosemide]	C		Unk	Not Reported
Prevnar 13	C	Intramuscular	0.5 Ml, Once	Not Reported
Sodium Chloride	C	Intravenous (not otherwise specified)	250 Ml	Not Reported
Sodium Chloride	C	Intravenous (not	30 Ml, Qd	Not Reported

		otherwise specified)		
Sodium Chloride	C	Intravenous (not otherwise specified)	250 Ml	Not Reported
Glucagen [Glucagon]	C	Intramuscular	1 Mg	Not Reported
Glucagen [Glucagon]	C	Intramuscular	1 Mg	Not Reported
Dextrose	C	Intravenous (not otherwise specified)	Unk	Not Reported
Dextrose	C	Oral	4 Dosage Form	Not Reported
K-Lor	C	Other	20 Meq, Once	Not Reported
K-Lor	C	Other	40 Meq, Once	Not Reported
Atropine Sulfate	C		Unk	Not Reported
Heparin Sodium	C	Subcutaneous	5000 Units Q 8 H	Not Reported
Aspirin [Acetylsalicylic Acid]	C	Other	325 Mg, Qd	Not Reported
Insulin Lispro	C	Subcutaneous	Unk	Not Reported
Magnesium Sulfate	C	Intravenous (not otherwise specified)	50 Ml, Once	Not Reported
Rocephine	C	Intravenous (not otherwise specified)	2 G, Qd	Not Reported
Zithromax	C	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
Definity	C	Intravenous (not otherwise specified)	Ud Prn	Not Reported
Midazolam Hcl	C	Intravenous (not otherwise specified)	2 Mg, Once	Not Reported
Midazolam Hcl	C	Intravenous (not otherwise specified)	Unk	Not Reported
Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
Insulin Regular [Insulin Bovine]	C	Subcutaneous	Unk Prn	Not Reported
Afrin [Oxymetazoline Hydrochloride]	C	Nasal	1 Spray Q 8 H Prn	Not Reported
Calcium Gluconate	C	Intravenous (not otherwise specified)	50 Ml, Once	Not Reported

Propofol	C		100 Ml	Not Reported
Propofol	C		100 Ml	Not Reported
Propofol	C		100 Ml	Not Reported
Sublimaze [Fentanyl Citrate]	C	Intravenous (not otherwise specified)	25 Mcg Q 2h Prn	Not Reported
Sublimaze [Fentanyl Citrate]	C	Intravenous (not otherwise specified)	Unk	Not Reported
Quelicin	C	Intravenous (not otherwise specified)	120 Mg	Not Reported
Quelicin	C		Unk Mg	Not Reported
Etomidate	C	Intravenous (not otherwise specified)	30 Mg	Not Reported
Plasma-Lyte A	C	Intravenous (not otherwise specified)	1000 Ml	Not Reported
Zofran [Ondansetron Hydrochloride]	C		Unk	Not Reported
Naloxone Hcl	C		Unk	Not Reported
Romazicon	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18172267	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0490924		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Creatinine Increased	Remdesivir			S	Unknown	Unk		Gilead
	Amiodarone			C		Unk		Not Reported
	Atorvastatin			C	Oral	40 Mg		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Cholecalciferol			C	Oral	2000 Iu		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Dutasteride			C		Unk		Not Reported

	Enoxaparin	C		Unk	Not Reported
	Famotidine	C		Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Lactulose	C		Unk	Not Reported
	Tamsulosin	C		Unk	Not Reported
	Thiamine	C		Unk	Not Reported
	Zinc Sulfate	C		Unk	Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	2 G	Not Reported
	Linezolid	C			Not Reported
	Meropenem	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18215511	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0492828		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Atrial Fibrillation; Cardio-Respiratory Arrest; Cardio-Respiratory Arrest; Covid-19 Pneumonia; Dehydration; Hyperphosphataemia; Respiratory Acidosis; Septic Shock	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Guaifenesin			C	Oral	600 Mg, Bid		Not Reported
	Zinc Acetate			C	Oral	500 Mg, Qd		Not Reported
	Vitamin D3			C	Oral	2000 Units		Not Reported
	Multivitamins;Minerals			C	Oral	1 Tab Daily		Not Reported
	Calcium Carbonate			C	Oral	500 Mg, Qd		Not Reported
	Lorazepam			C	Oral	0.5mg Hsprn		Not Reported
	Acetaminophen			C	Rectal	650 Mg As Needed		Not Reported
	Benzonatate			C	Oral	200 Mg, Tid Prn		Not Reported
	Carbamazepine			C	Oral	300 Mg, Tid		Not Reported
	Dexamethasone			C	Intravenous (not	6 Mg, Qd		Not Reported

			otherwise specified)		
	Enoxaparin	C	Subcutaneous	80 Mg, Bid	Not Reported
	Famotidine	C	Oral	20 Mg, Qd	Not Reported
	Lamotrigine	C	Oral	100 Mg, Qd	Not Reported
	Olanzapine	C	Intramuscular	5 Mg Hs Prn	Not Reported
	Olanzapine	C			Not Reported
	Azithromycin	C		Unk	Not Reported
	Diltiazem	C	Intravenous (not otherwise specified)	10 Mg, Once	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	2 G, Qd	Not Reported
	Metoprolol Tartrate	C	Intravenous (not otherwise specified)	10 Mg, Once	Not Reported
	Propofol	C	Intravenous (not otherwise specified)	20-40 Mcg/Kg/Min	Not Reported
	Heparin	C	Intravenous (not otherwise specified)	600-1050 Unit/Hr	Not Reported
	Epoprostenol [Epoprostenol Sodium]	C	Intravenous (not otherwise specified)	2ng/Kg/Min	Not Reported
	Sevelamer	C	Oral	800 Mg, Tid	Not Reported
	Insulin Aspart	C			Not Reported
	Potassium Phosphate [Potassium Phosphate Dibasic]	C			Not Reported
	Red Blood Cells	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18218293	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0492628		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C		325 Mg		Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported

	Azithromycin			C					Not Reported
	Ceftriaxone			C					Not Reported
	Dexamethasone			C					Not Reported
	Docusate Sodium			C					Not Reported
	Heparin			C					Not Reported
	Insulin Glargine			C					Not Reported
	Pantoprazole			C					Not Reported
	Peg 3350			C		17 G			Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18269743	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0494929		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19; Embolism Venous; Gastrointestinal Haemorrhage; Multiple Organ Dysfunction Syndrome; Pulmonary Embolism; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa			C	Respiratory (inhalation)	2 Puff Inhaled 4x/Day		Not Reported
	Amiodarone			C	Oral	200 Mg, Qd		Not Reported
	Calcium Gluconate			C	Intravenous (not otherwise specified)	1 G		Not Reported
	Rocuronium			C		Unk, Continious Infusion		Not Reported
	Docusate			C	Oral	50 Mg, Bid		Not Reported
	Heparin			C	Subcutaneous	5000 Units, Q8h		Not Reported
	Lidocaine			C	Topical	4 % (Topical Patch)		Not Reported
	Levothyroxine			C		100 Mcg, Qd		Not Reported
	Vasopressin			C		Unk, Continous Infusion		Not Reported
	Midazolam			C		Unk, Continious Infusion		Not Reported
	Protonix [Omeprazole]			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Dulera			C		2 Puff, Bid		Not Reported
	Miralax			C		17 G, Bid		Not Reported

		Pyridostigmine			C	Oral	120 Mg, Tid			Not Reported
		Sodium Bicarbonate			C		650 Mg, Bid			Not Reported
		Lokelma			C	Oral	10 G, Qd			Not Reported
		Artificial Tears [Glycerol; Hypromellose;Macrogol]			C		Unk, Q4hr			Not Reported
		Folan			C	Respiratory (inhalation)	Unk			Not Reported
		Fentanyl			C		Unk, Continious Infusion			Not Reported
		Norepinephrine			C		Unk, Continious Infusion			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18270685	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0494944		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Pneumonia Bacterial	Remdesivir			S	Unknown	100 Mg		Gilead
	Lidocaine			C		Unk		Not Reported
	Lorazepam			C	Intravenous (not otherwise specified)	1 Mg, Qd		Not Reported
	Lorazepam			C	Intravenous (not otherwise specified)	2 Mg		Not Reported
	Nystatin			C	Topical	100,000 Units		Not Reported
	Hydromorphone			C		Unk		Not Reported
	Oxygen			C				Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18273968	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0495164		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not	100 Mg, Qd		Gilead

		otherwise specified)		
Azithromycin	S	Unknown	Unk	Not Reported
Cefepime	S	Unknown	Unk	Not Reported
Vancomycin	S	Unknown	Unk	Not Reported
Tocilizumab	C		Unk	Not Reported
Tocilizumab	C		Unk	Not Reported
Aspirin (E.C.)	C		Unk	Not Reported
Vitamin D3	C		Unk	Not Reported
Dexamethasone	C		Unk	Not Reported
Diphenhydramine	C		Unk	Not Reported
Enoxaparin	C		Unk	Not Reported
Furosemide	C		Unk	Not Reported
Furosemide	C		Unk	Not Reported
Iopamidol	C		Unk	Not Reported
Iopamidol	C		Unk	Not Reported
Levaquin	C		Unk	Not Reported
Zyvox	C		Unk	Not Reported
Lorazepam	C		Unk	Not Reported
Merrem	C		Unk	Not Reported
Merrem	C		Unk	Not Reported
Solu Medrol	C		Unk	Not Reported
Align	C			Not Reported
Pulmicort	C			Not Reported
Klonopin	C		0.5 Mg	Not Reported
Vibra [Doxycycline]	C			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C		200 Mg	Not Reported
Probiotic 10	C			Not Reported
Intrinsi B12/Folate	C			Not Reported
Zinc Acetate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306293	DIRECT	Y	HO			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Haemodialysis; Liver Function Test Increased; Renal Failure; Urine Output Decreased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306336	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; General Physical Health Deterioration; Hepatotoxicity; Hypotension; Hypovolaemia; Hypoxia; Multiple Organ Dysfunction Syndrome; Respiratory Failure; Thrombosis	Remdesivir	Y		S	Intravenous drip			Gilead
	Amiodarone			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306772	DIRECT	Y	DE			93 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Palliative Care	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306798	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18306829	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir	Y		S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307274	DIRECT	Y	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:X 1 Dose On Day 1;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307340	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18307400	DIRECT		OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18311115	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0496060		63 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Remdesivir			S	Unknown	5 Mg/Kg, Qd		Gilead
	Remdesivir			S	Unknown	2.5 Mg/Kg, Qd		Gilead
	Piperacillin & Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18311343	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Dialysis; Therapy Cessation; Transaminases Increased	Remdesivir			S	Intravenous drip		6 DAY	Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Midazolam			C				Not Reported
	Morphine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
	Labetalol			C				Not Reported
	Succinylcholine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18311859	DIRECT	Y				38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension	Remdesivir			S				Not Reported
	Lactulose			S				Not Reported
	Metoclopramide			S				Not Reported
	Albuterol			S				Not Reported
	Ascorbic Acid			S				Not Reported

	Baclofen	S		Not Reported
	Bisacodyl	S		Not Reported
	Symbicort	S		Not Reported
	Ceftriaxone	S		Not Reported
	Cetirizine	S		Not Reported
	Vitamin D3	S		Not Reported
	Dexamethasone	S		Not Reported
	Doxycycline	S		Not Reported
	Enoxaparin	S		Not Reported
	Gabapentin	S		Not Reported
	Midodrine	S		Not Reported
	Oxybutynin	S		Not Reported
	Oxycodone	S		Not Reported
	Miralax	S		Not Reported
	Senna Plus	S		Not Reported
	Zinc Gluconate	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18311884	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Atrial Fibrillation; Blood Creatinine Increased; Blood Pressure Decreased; Cha2ds2-Vasc-Score; Condition Aggravated; Confusional State; Dyspnoea; Heart Rate Decreased; Hypoxia; Lethargy; Lung Infiltration; Oxygen Saturation Decreased; Renal Disorder	Remdesivir 200 Mg			S	Intravenous (not otherwise specified)	Frequency: Day 1		Gilead
	Remdesivir 100mg			S	Intravenous (not otherwise specified)	Frequeny: Day 2-5		Gilead
	Covid-19 Convalescent Plasma			C				Not Reported
	Carvedilol			C				Not Reported
	Amiodarone			C				Not Reported
	Gabapentin			C				Not Reported
	Pantoprazole			C				Not Reported
	Lovenox			C				Not Reported
	Aspirin			C				Not Reported
	Plavix			C				Not Reported
	Simvastatin			C				Not Reported
	Beta-Blockers			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Levimir			C				Not Reported
	Levimir			C				Not Reported
	Novolog			C				Not Reported

	Decadron			C	Intravenous (not otherwise specified)	Other Frequency:Qday ;			Not Reported
	Covid-19 Convalescent Plasma			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18312156	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Electrocardiogram Change	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Levothyroxine			C				Not Reported
	Metoprolol			C				Not Reported
	Ns			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2020	18312408	DIRECT	Y				59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported
	Potassium Tablets			C				Not Reported
	Bicarbonate Tablets			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Benzonatate			C				Not Reported
	Budesonide			C				Not Reported
	Vitamin D3			C				Not Reported
	Robitussin Dm			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Sliding Scale Insulin			C				Not Reported
	Synthroid			C				Not Reported
	Protonix			C				Not Reported
	Senna Plus			C				Not Reported
	Zocor			C				Not Reported

	Zinc Gluconate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18143332	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0489778		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Acute Respiratory Failure; Covid-19; Multi-Organ Disorder; Pneumonia; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Oxygen			C				Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	100 Mcg/Hr		Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	50 Mcg/Min		Not Reported
	Vasopressin			C	Intravenous (not otherwise specified)	0.03 U/Min		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	1 G		Not Reported
	Enoxaparin			C	Subcutaneous	65 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18219319	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0492675		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C	Unknown	6 Mg, Qd		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Albuterol			C		Inhaler, 2 Puffs		Not Reported
	Guaifenesin			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported

	Insulin	C	Sliding Scale Sq Ac And Hs	Not Reported
	Lantus	C	16 Units Sq Daily	Not Reported
	Melatonin	C	5 Mg Po Hs Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18259446	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0494634		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Lidocaine [Chlorhexidine; Lidocaine]			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Nifedipine			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Ascorbic Acid			C				Not Reported
	Cefepime			C				Not Reported
	Cholecalciferol			C				Not Reported
	Heparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Maalox Antacid			C				Not Reported

	Aspirin (E.C.)			C					Not Reported
	Enalapril			C					Not Reported
	Insulin Lispro			C					Not Reported
	Lidocaine			C					Not Reported
	Ondansetron			C					Not Reported
	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18280607	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0495325		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Loratadine			C				Not Reported
	Omeprazole			C		Unk		Not Reported
	Sildenafil			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Plasma			C				Not Reported
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18311811	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Benzonatate			C				Not Reported
	Dexamethasone			C				Not Reported
	Enxoaparin			C				Not Reported
	Metoprolol Succinate			C				Not Reported

	Rosuvastatin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312144	DIRECT	Y				35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Remdesivir			S				Not Reported
	Apap			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Ketorolac			C				Not Reported
	Mylanta			C				Not Reported
	Morphine			C				Not Reported
	Ondansetron			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported
	Azithromycin			C				Not Reported
	Saline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312226	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia	Remdesivir			S				Not Reported
	Thiamine			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Culurelle			C				Not Reported
	Subq Heparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriazone			C				Not Reported
	Iv Azithromycin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Potassium Bicarbonate			C				Not Reported
	Hycodan			C				Not Reported
	Benzonatate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312230	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neck Pain; Swelling	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone 6 Mg			C				Not Reported
	Hycodan			C				Not Reported
	Lovenox 50mg			C				Not Reported
	Ascorbic Acid 500 Mg			C				Not Reported
	Metoprolol 25 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312707	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Poor Quality Product Administered; Product Storage Error	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Acetaminophen 650 Mg Ng Once			C				Not Reported
	Cefepime 1g Iv Q8h			C				Not Reported
	Cisatracurium 100 Mg Iv Infusion			C				Not Reported
	Dexamethasone 6 Mg Iv Q24h			C				Not Reported
	Diltiazem 10 Mg Iv Once			C				Not Reported
	Enoxaparin 80 Mg Sc Q12h			C				Not Reported
	Famotidine 20 Mg Iv Q12h			C				Not Reported
	Fentanyl 25 Mcg/Ml- 100 Ml Iv Infusion			C				Not Reported
	Norepinephrine 8 Mg Iv Infusion			C				Not Reported
	Propofol 1000 Mg/100 Ml Iv Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312712	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Cardiogenic Shock; Polyuria	Remdesivir	S	Intravenous (not otherwise specified)		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312866	DIRECT	Y				16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312869	DIRECT	Y	HO, LT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fluoxetine			C				Not Reported
	Lisinopril			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312909	DIRECT		OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Hyperhidrosis; Hypertension; Hypoaesthesia; Rash	Veklury Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312912	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18312920	DIRECT	Y				87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Not Reported
	Enoxaparin			C				Not Reported
	Etomidate			C				Not Reported
	Furosemide			C				Not Reported
	Ampicillin/Sulbactam			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Atenolol			C				Not Reported
	Albumin			C				Not Reported
	Azithromycin			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Colchicine			C				Not Reported
	Dexamethasone			C				Not Reported
	Digoxin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Glargine			C				Not Reported
	Lactulose			C				Not Reported
	Midodrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Theophylline			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18317844	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dyspnoea; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Acetaminophen			C				Not Reported
	Codeine-Guaifenesin			C				Not Reported
	Lorazepam			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18318071	DIRECT	Y				79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Home Medications (Not Further Specified)			C				Not Reported
	Dexamethasone			C		Other Route:Iv		Not Reported
	Vancomycin			C				Not Reported
	Cefepime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18318242	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Blood	Remdesivir			S				Not Reported
	Aspirin			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Pantoprazole			C				Not Reported
	Finasteride			C				Not Reported
	Furosemide			C				Not Reported
	Amlodipine			C				Not Reported
	Carvedilol			C				Not Reported

Potassium Increased; International Normalised Ratio Increased; Metabolic Encephalopathy; Septic Shock	Atorvastatin	C	Not Reported
	Ascorbic Acid	C	Not Reported
	Nitroglycerin	C	Not Reported
	Zinc	C	Not Reported
	Cholecalciferol	C	Not Reported
	Acetaminophen	C	Not Reported
	Insulin Lispro	C	Not Reported
	Azithromycin	C	Not Reported
	Ceftriaxone	C	Not Reported
	Dexamethasone	C	Not Reported
	Labetalol	C	Not Reported
	Ipratropium/Albuterol	C	Not Reported
	Budesonide	C	Not Reported
	Enoxaparin	C	Not Reported
	Oxycodone/Acetaminophen	C	Not Reported
	Propofol	C	Not Reported
	Fentanyl	S	Not Reported
	Midazolam	C	Not Reported
	Etomidate	C	Not Reported
	Succinylcholine	C	Not Reported
	Cefepime	C	Not Reported
	Tocilizumab	C	Not Reported
	Hydralazine	C	Not Reported
	Amlodipine	C	Not Reported
	Apixaban	C	Not Reported
	Aspirin	C	Not Reported
	Atorvastatin	C	Not Reported
	Azithromycin	C	Not Reported
	Carvedilol	C	Not Reported
	Cetirizine	C	Not Reported
	Coenzyme Q	C	Not Reported
	Dextromethorphan/Guaifenesin	C	Not Reported
	Diclofenac	C	Not Reported
	Finasteride	C	Not Reported
	Furosemide	C	Not Reported
	Lorazepam	C	Not Reported
	Metronidazole Cream	C	Not Reported
	Mvi	C	Not Reported
	Omega-3 Fatty Acids	C	Not Reported
	Omeprazole	C	Not Reported
	Prednisone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2020	18318247	DIRECT	Y	HO			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Tocilizumab			C				Not Reported
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2020	18321777	DIRECT		OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Liver Function Test Increased; Rash Maculo-Papular	Remdesivir			S		Duration: 10 Days(Stoped After 4)	10 DAY	Not Reported
						Duration: 10 Days (Stopped After 4)	10 DAY	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18329333	DIRECT		DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Lung Disorder; Lung Opacity; Multiple Organ Dysfunction Syndrome; Pleural Effusion; Pulmonary Mass; Sepsis	Remdesivir			S				Not Reported
	Colimycin			C				Not Reported
	Isavuconazole			C				Not Reported
	Levofloxacin			C				Not Reported
	Meropenem			C				Not Reported
	Tigecycline			C				Not Reported
	Voriconazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2020	18329984	DIRECT		OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Beta-D-Glucan Positive; Bronchoalveolar Lavage Abnormal; Candida Test Positive; Off Label Use	Remdesivir			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	17960463	EXPEDITED (15-DAY)		DE, HO, LT, OT	NL-MYLANLABS-2020M1059896			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Barotrauma; Pneumonia	Furosemide			S		Unk		Mylan
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Mylan
	Paracetamol			C	Oral	Unk		Mylan
	Noradrenaline /00127502/			C	Intravenous (not otherwise specified)	Unk		Mylan
	Remifentanil			C	Intravenous (not otherwise specified)	Unk		Mylan
	Ceftriaxon			C	Intravenous (not otherwise specified)	Unk		Mylan
	Movicolon			C	Oral	Unk		Mylan
	Nadroparin			C	Subcutaneous	Unk		Mylan
	Cisatracurium			C	Intravenous (not otherwise specified)	Unk		Mylan
	Propofol			C	Intravenous (not otherwise specified)	Unk		Mylan
	Supradyn /07499601/			C	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18259416	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0494650		98 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Atrial Fibrillation; Gastrointestinal Haemorrhage; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Benicar			C	Oral	40 Mg		Not Reported
	Calcium			C	Oral	500 Mg		Not Reported
	Cardizem [Diltiazem]			C	Oral	90 Mg		Not Reported
	Clonidine			C	Oral	0.1 Mg		Not Reported
	Colace			C	Oral	100 Mg		Not Reported
	Decadron [Dexamethasone]			C	Intravenous (not otherwise specified)	4 Mg		Not Reported
	Lotensin [Timolol Maleate]			C	Oral	40 Mg		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous	50 Mg		Not Reported
	Minoxidil			C	Oral	5 Mg		Not Reported
	Myrbetriq			C	Oral	50 Mg		Not Reported
	Neurontin			C	Oral	200 Mg		Not Reported
	Neurontin			C	Oral	100 Mg		Not Reported
	Norvasc			C	Oral	5 Mg		Not Reported
	Pepcid [Famotidine]			C	Oral	40 Mg		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]			C	Oral			Not Reported
	Protonix [Omeprazole]			C		40 Mg		Not Reported
	Rocephin [Ceftriaxone]			C	Intravenous (not otherwise specified)	1 G		Not Reported
	Symbicort			C	Respiratory (inhalation)			Not Reported
	Sodium Chloride 0.9%			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18275000	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0495260		45 YR	Female	USA

| Preferred Term | Product | Comp. | OTC | Role | Route | Dosage Text | Duration | Mfr |

Acute Kidney Injury; Aspartate Aminotransferase Increased; Atrial Fibrillation; Cardiac Arrest; Disseminated Intravascular Coagulation; Fungal Infection; Liver Function Test Increased; Shock; Ventricular Tachycardia	Remdesivir	S	Unknown	100 Mg, Qd	Gilead
	Vancomycin	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Warfarin	C			Not Reported
	Cefepime	C			Not Reported
	Definity	C		Unk	Not Reported
	Duoneb	C	Respiratory (inhalation)	3 Ml, Q6h	Not Reported
	Insulin Regular Hm	C	Subcutaneous	Unk	Not Reported
	Keppra	C	Intravenous (not otherwise specified)	500 Mg, Bid	Not Reported
	Lipitor [Atorvastatin]	C	Other	10 Mg, Qd	Not Reported
	Maxipime	C	Intravenous (not otherwise specified)	2 G, Bid	Not Reported
	Protonix [Omeprazole]	C	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported
	Metronidazole	C	Intravenous (not otherwise specified)	100 Ml, Q84hr	Not Reported
	Kcentra	C			Not Reported
	Vit K1	C			Not Reported
	Platelets	C	Intravenous (not otherwise specified)	2 Units	Not Reported
	Red Blood Cells	C		2 Units	Not Reported
	Lasix [Furosemide]	C	Intravenous (not otherwise specified)	40 Mg, Once	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18280600	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0495310		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Chlorhexidine			C				Not Reported

		Dexamethasone			C					Not Reported
		Enoxaparin			C					Not Reported
		Fentanyl			C					Not Reported
		Magnesium Sulfate			C					Not Reported
		Midazolam			C					Not Reported
		Piperacillin & Tazobactam			C					Not Reported
		Vancomycin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319022	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319038	DIRECT	Y	OT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319043	DIRECT	Y				54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319057	DIRECT					64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319149	DIRECT					77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319164	DIRECT	Y	HO			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319190	DIRECT	Y				81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Transcription Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319192	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Paravenous Drug	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Sodium Chloride 0.9%			C				Not Reported

Administration

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18319572	EXPEDITED (15-DAY)		OT	NL-TEVA-2020-NL-1830680		57 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Codeine Tablet 10mg / Brand Name Not Specified			S		1 Tablet Twice Daily And 2 Tablets At 22:00, 1 Dosage Form		Not Reported
	Azitromycine Tablet 500mg / Brand Name Not Specified			S		500 Milligram Daily;		Not Reported
	Remdesivir			S		100 Milligram Daily;		Not Reported
	Enoxaparine Injvlst 10.000ie/Ml (100mg/Ml) / Clexane Injvlst 2.000ie			C		10,000 Iu / Ml, 1 Dosage Form, Therapy Start Date And End Date: Asked But Unknown		Not Reported
	Oxazepam Tablet 10mg / Brand Name Not Specified			C		10 Mg, Therapy Start Date And End Date: Asked But Unknown		Not Reported
	Pantoprazol Tablet Msr 40mg / Brand Name Not Specified			C		40 Mg , Therapy Start Date And End Date: Asked But Unknown		Not Reported
	Dexamethason Injvlst 1mg/Ml (Base) / Brand Name Not Specified			C		1 Dosage Form, Therapy Start Date And End Date: Asked But Unknown		Not Reported
	Ceftriaxon Infusiepoeder 2000mg / Brand Name Not Specified			C		2000 Mg, Therapy Start Date And End Date: Asked But Unknown		Not Reported
	Loperamide Capsule 2mg / Brand Name Not Specified			C		2 Mg, Therapy Start Date And End Date: Asked But Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18322061	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18322083	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported
	Famotidine			C				Not Reported
	Guaifenesin			C				Not Reported
	Zofran			C				Not Reported
	Normal Saline			C				Not Reported
	Oxycodone			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18322093	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18322700	DIRECT	Y	OT			20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukocytosis; Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	Other Dose:200mgx1d, 100mgx2d;		Gilead

	Citalopram			C					Not Reported
	Fluticasone			C					Not Reported
	Levothyroxine			C					Not Reported
	Spironolactone			C					Not Reported
	Warfarin			C					Not Reported
	Hydroxyzine			C					Not Reported
	Lorazepam			C					Not Reported
	Ondansetron			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18338601	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arrhythmia; Aspartate Aminotransferase Increased; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Torsade De Pointes	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)		9 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2020	18364486	DIRECT		DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Blood Creatinine Increased; Blood Culture Positive; Culture Urine Positive; Diffuse Alveolar Damage; Enterococcal Infection; Fibrin D Dimer Increased; Product Use In Unapproved Indication; Pulmonary Embolism; Respiratory Failure;	Remdesivir			S			10 DAY	Not Reported

Staphylococcal Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18045905	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483722		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Mg		Not Reported
	Dexamethasone			C	Oral	6 Mg		Not Reported
	Ascorbic Acid			C	Oral	500 Mg		Not Reported
	Cholecalciferol			C	Oral	5000 U		Not Reported
	Famotidine			C	Oral	20 Mg		Not Reported
	Furosemide			C	Oral	20 Mg		Not Reported
	Memantine			C	Oral	10 Mg		Not Reported
	Primidone			C	Oral	250 Mg		Not Reported
	Xarelto			C	Oral	20 Mg		Not Reported
	Topiramate			C	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18170971	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0490887		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Death	Remdesivir			S	Unknown	Unk		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18322747	DIRECT	Y	OT			53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Distension; Abdominal Pain; Fatigue; Flatulence; Hepatic Enzyme Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323074	DIRECT	Y	OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Therapy Interrupted	Remdesivir Intravenous Powder For Solution			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Buprenophine-Naloxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Phytonadione			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323378	DIRECT		OT			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Mucous Stools	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin 81mg			C				Not Reported
	Vitamin C 500mg			C				Not Reported
	Zinc 50mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18323383	DIRECT	Y				38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported
	Azithromycin 500 Mg Iv Q24h			C				Not Reported
	Cefepime 2 Gm Iv Q8h			C				Not Reported
	Ceftriaxone 2 Gm Iv Q24h			C				Not Reported
	Dexamethasone 6 Mg Iv Q24h			C				Not Reported
	Enoxaparin Sq			C				Not Reported
	Furosemide			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324065	DIRECT	Y				24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324074	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tylenol			C				Not Reported
	Vitamin C			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Docusate			C				Not Reported

			Senna		C					Not Reported
			Lovenox		C					Not Reported
			Lactated Ringers		C					Not Reported
			Famotidine		C					Not Reported
			Furosemide		C					Not Reported
			Hydralazine		C					Not Reported
			Insulin Aspart		C					Not Reported
			Methylprednisolone		C					Not Reported
			Zosyn		C					Not Reported
			Tocilizumab		C					Not Reported
			Vancomycin		C					Not Reported
			Zinc Sulfate		C					Not Reported
			Potassium Chloride		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324086	DIRECT	Y				72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324092	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypoperfusion; Hypovolaemia; Large Intestine Perforation	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Tocilizumab			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid 1,500 Mg Q6h Iv			C				Not Reported
	Aspirin Ec			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone Na Phos			C				Not Reported
	Enoxaparin			C				Not Reported
	Gabapentin			C				Not Reported

		Hydrochlorothiazide			C					Not Reported
		Insulin (Glargine, Lispro, And Sliding-Scale Regular)			C					Not Reported
		Lisinopril			C					Not Reported
		Magnesium Oxide			C					Not Reported
		Metformin			C					Not Reported
		Metoprolol			C					Not Reported
		Ondansetron			C					Not Reported
		Potassium Chloride Er Tablets			C					Not Reported
		Sodium Chloride 0.9% Drip			C					Not Reported
		Zinc Sulfate (Oral)			C					Not Reported
		Zosyn			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324652	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Actemra			C				Not Reported
	Vitamin C			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Vitamin D3			C				Not Reported
	Lovenox			C				Not Reported
	Probiotic			C				Not Reported
	Multivitamin			C				Not Reported
	Protonix			C				Not Reported
	Neutra-Phos			C				Not Reported
	Vitamin A			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Acetaminophen			C				Not Reported
	Fioricet			C				Not Reported
	Morphine			C				Not Reported
	D5-Lactated Ringers			C				Not Reported
	Lactated Ringers			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324699	DIRECT	Y				37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		4 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18324719	DIRECT	Y	HO, OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)		8 DAY	Not Reported
	Atorvastatin 20mg			C				Not Reported
	Cefepime 2g In 100ml			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Enoxaparin 40mg			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Oxycodone Ir 5 Mg			C				Not Reported
	Pantoprazole 40mg			C				Not Reported
	K Phos Neutral 155-852-130mg			C				Not Reported
	Polyethylene Glycol 17g			C				Not Reported
	Propofol Infusion			C				Not Reported
	Vitamin D 25 Mcg			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18327467	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0496563		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Transaminases Increased	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported

	Heparin	C	Unk	Not Reported
	Midazolam	C	Unk	Not Reported
	Morphine	C	Unk	Not Reported
	Pantoprazole	C	Unk	Not Reported
	Propofol	C	Unk	Not Reported
	Labetalol	C	Unk	Not Reported
	Succinylcholine [Suxamethonium]	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18328555	DIRECT	Y	DE			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Band Neutrophil Count Increased; Blood Bilirubin Increased; Blood Calcium Decreased; Blood Creatinine Increased; Blood Glucose Decreased; Blood Magnesium Increased; Blood Sodium Increased; Blood Urea Increased; Bradycardia; Carbon Dioxide Decreased; Cardiac Arrest; Cardiac Disorder; Dialysis; Glomerular Filtration Rate; Haematocrit Decreased; Haemodialysis; Haemoglobin Decreased; Hypochromasia; Hypokalaemia;	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 1000 Mg Po Bid			C				Not Reported
	Ascorbic Acid 1000 Mg Po Bid			C				Not Reported
	Azithromycin 500 Mg Iv Once Daily			C				Not Reported
	Azithromycin 500 Mg Iv/Po Once Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Ceftriaxone 2 Gm Iv Once Daily			C				Not Reported
	Ceftaroline 600 Mg Iv Q12hrs			C				Not Reported
	Cholecalciferol 2,000 Units Po Once Daily			C				Not Reported
	Colchicine 0.6 Mg Po Bid			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Zinc Sulfate 220 Mg Po Once Bid			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Enoxaparin 30 Mg Sq Q12hr			C				Not Reported
	Enoxaparin 80 Mg Sq Q12hr			C				Not Reported
	Famotidine 20 Mg Po Q12hr			C				Not Reported
	Pantoprazole/Omeprazole Po			C				Not Reported
	Meropenem Renally Dosed			C				Not Reported

Hyponatraemia; Hypotension; Lymphocyte Count Decreased; Macrocytosis; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Metabolic Acidosis; Metamyelocyte Count Increased; Monocyte Count Decreased; Neutrophil Count Increased; Neutrophil Toxic Granulation Present; Platelet Count Decreased; Pupil Fixed; Red Blood Cell Count Decreased; Respiratory Failure; Unresponsive To Stimuli	Micafungin 100 Mg Iv Once Daily	C	Not Reported
	Pip/Tazo 3.375 Gm Iv Q8hr	C	Not Reported
	Vancomycin Per Protocol	C	Not Reported
	Insulin Glargine/Lispro	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18328560	DIRECT	Y				79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Refusal Of Treatment By Patient	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18328567	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18328573	DIRECT	N	DE				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2020	18329186	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18224931	EXPEDITED (15-DAY)		DE	BR-ROCHE-2668685		66 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Septic Shock	Tocilizumab			S	Intravenous (not otherwise specified)	This Was The Most Recent Dose Of Blinded Tocilizumab Administered Prior To Ae/Sae Onset At 07:20 Hou		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	On 27/Aug/2020, At 11:47 Hours; Most Recent Dose (20 Ml) Of Remdesivir Administered Prior To Ae/Sae		Not Reported
	Azithromycin			C				Not Reported
	Prednisolone			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Eliquis			C				Not Reported
	Clarithromycin			C				Not Reported
	Esomeprazole			C				Not Reported
	Decadron			C				Not Reported
	Moxifloxacin			C				Not Reported

	Duoflam (Brazil)	C	1 Amplue	Not Reported
	Metformin	C		Not Reported
	Enoxaparin	C		Not Reported
	Enoxaparin	C		Not Reported
	Ceftriaxone	C		Not Reported
	Methylprednisolone	C		Not Reported
	Midazolam	C		Not Reported
	Epinephrine	C		Not Reported
	Fentanyl	C		Not Reported
	Fentanyl	C		Not Reported
	Omeprazole	C		Not Reported
	Hydrocortisone	C		Not Reported
	Nitroglycerin	C		Not Reported
	Dobutamine	C		Not Reported
	Rocuronium	C		Not Reported
	Acetylcysteine	C		Not Reported
	Ascorbic Acid	C	1 Ampule	Not Reported
	Haldol	C		Not Reported
	Digoxin	C		Not Reported
	Furosemide	C		Not Reported
	Losartan	C		Not Reported
	Amlodipine	C		Not Reported
	Insulin	C		Not Reported
	Insulin	C		Not Reported
	Nitroprusside	C		Not Reported
	Water-Soluble Vitamins	C	1	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18275634	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0495155		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
	Hydroxychloroquine			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Tacrolimus			C				Not Reported
	Dexamethasone			C		Unk		Not Reported

Acetaminophen	C	Unk	Not Reported
Aluminum Hydroxide [Aluminium Hydroxide]	C	Unk	Not Reported
Albuterol [Salbutamol Sulfate]	C	Unk	Not Reported
Amlodipine	C	Unk	Not Reported
Azithromycin	C	Unk	Not Reported
Calcium Gluconate	C	Unk	Not Reported
Chlorhexidine	C	Unk	Not Reported
Clonidine	C	Unk	Not Reported
Cyclophosphamide	C	Unk	Not Reported
Desmopressin	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Diazepam	C	Unk	Not Reported
Docusate Sodium & Senna	C	Unk	Not Reported
Enoxaparin	C		Not Reported
Etomidate	C	Unk	Not Reported
Famotidine	C		Not Reported
Fentanyl	C	Unk	Not Reported
Ondansetron	C	Unk	Not Reported
Oxycodone	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Piperacillin & Tazobactam	C	Unk	Not Reported
Prochlorperazine	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Sevelamer	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18280598	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0495297		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Dexamethasone	C		Unk		Not Reported
	Enoxaparin	C				Not Reported
	Iopamidol	C				Not Reported
	Fluticasone Furoate;Vilanterol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18327039	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2020SP010651		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Off Label Use	Oseltamivir			S	Unknown	Unk		Strides
	Oseltamivir			S				Strides
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Betamethasone			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329323	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329351	DIRECT	Y	DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329718	DIRECT	Y	DE			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure; Road Traffic Accident	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329872	DIRECT	Y	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18329878	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331287	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0496699		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Nausea	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18331902	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0496881		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported

	Ceftriaxone	C	Not Reported
	Ceftaroline	C	Not Reported
	Cholecalciferol	C	Not Reported
	Colchicine	C	Not Reported
	Dexamethasone	C	Not Reported
	Zinc Sulfate	C	Not Reported
	Plasma	C	Not Reported
	Enoxaparin	C	Not Reported
	Famotidine	C	Not Reported
	Pantoprazole	C	Not Reported
	Omeprazole	C	Not Reported
	Meropenem	C	Not Reported
	Micafungin	C	Not Reported
	Piperacillin / Tazobactam	C	Not Reported
	Vancomycin	C	Not Reported
	Insulin Glargine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18333607	DIRECT	Y	OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic; Transaminases Increased	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18333611	DIRECT	Y	OT			82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Heart Rate Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18333616	DIRECT	Y	HO, LT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S				Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18333622	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Paravenous Drug Administration	Remdesivir	Y		S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18333627	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Fungaemia; Hyponatraemia; Hypovolaemic Shock; Pneumonia; Pneumothorax; Pupil Fixed; Respiratory Failure; Septic Shock; Supraventricular Tachycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 1000mg Po Tid			C				Not Reported
	Azithromycin 500mg Po Once Daily			C				Not Reported
	Cefepime 1 Gm Iv Q6hr			C				Not Reported
	Cefepime 1 Gm Iv Q8hr			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Dexamethasone 10mg Iv Once Daily			C				Not Reported
	Dexamethasone 6mg, 10mg Iv Once Daily			C				Not Reported
	Meropenem Iv Renally Adjusted			C				Not Reported
	Meropenem 1 Gm Iv Q8hr			C				Not Reported
	Zinc Sulfate 220mg Po Bid			C				Not Reported
	Vancomycin Per Protocol			C				Not Reported
	Vancomycin 1500mg Iv Once			C				Not Reported
	Micafungin 100mg Iv Once Daily			C				Not Reported
	Micafungin 100mg Iv Once Daily			C				Not Reported

	Famotidine 20mg Po Q12hr	C	Not Reported
	Convalescent Plasma	C	Not Reported
	Enoxaparin 70mg Sq Q12hr	C	Not Reported
	Enoxaparin 40mg Sq Once Daily	C	Not Reported
	Enoxaparin 60mg Sq Q12hr	C	Not Reported
	Methylprednisolone 60mg Iv Q12hr, 40mg Iv Q12hr	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2020	18333634	DIRECT	Y	DE			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basophil Percentage Decreased; Blood Bicarbonate Decreased; Blood Calcium Decreased; Blood Creatinine Increased; Blood Glucose Increased; Blood Ph Decreased; Blood Phosphorus Increased; Blood Urea Increased; Carbon Dioxide Decreased; Eosinophil Percentage Decreased; Glomerular Filtration Rate Decreased; Haematocrit Decreased; Haemoglobin Decreased; Hypoxia; Immature Granulocyte Count Increased; Lymphocyte Count Increased; Mean Cell Haemoglobin Concentration Decreased; Mean Platelet Volume Increased; Monocyte Percentage Decreased; Neutrophil Count Increased; Neutrophil	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Azithromycin 500 Mg Iv/Po			C				Not Reported
	Ceftriaxone 2 Gm Iv Once Daily			C				Not Reported
	Clopidogrel 75 Mg Po Once Daily			C				Not Reported
	Amiodarone Iv Drip			C				Not Reported
	Asa 325 Mg X1, Then 81 Mg Po Once Daily			C				Not Reported
	Cefepime 1 Gm Iv Q8hr			C				Not Reported
	Enoxaparin 150 Mg X 3 Ddose, Then 200 Mg Sq Bid			C				Not Reported
	Famotidine 20 Mg Iv/Po Renally Dosed			C				Not Reported
	Gabapentin 600 Mg Po Bid			C				Not Reported
	Meropenem 500 Mg Iv Q12hr			C				Not Reported
	Micafungin 100 Mg Iv Once Daily			C				Not Reported
	Vancomycin Per Protocol			C				Not Reported

Percentage Increased; Oxygen Saturation Decreased; Pco2 Increased; Red Blood Cell Count Decreased; Red Cell Distribution Width Decreased; Respiratory Acidosis; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18229184	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05213		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Dexamethasone			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18229205	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-05221		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Oseltamivir			S	Unknown	Unk		Lupin
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18270943	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0494951		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir			S	Intravenous (not	200 Mg, Once		Gilead

Increased; Aspartate Aminotransferase Increased				otherwise specified)			
	Remdesivir		S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone		C	Intravenous (not otherwise specified)	6 Mg		Not Reported
	Acetaminophen		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18275985	EXPEDITED (15-DAY)		DE	BR-ROCHE-2672737		77 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Sepsis; Sepsis	Tocilizumab			S	Intravenous (not otherwise specified)	Loading Dose		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Loading Dose On 05/Sep/2020, At 11:20, Most Recent Dose Of Intravenous Remdesivir (250 Ml) Was Admin		Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Rocuronium			C				Not Reported
	Furosemida			C				Not Reported
	Omeprazole			C				Not Reported
	Ketamine			C				Not Reported
	Norepinefrina			C				Not Reported
	Lactulose			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported
	Meropenem			C				Not Reported
	Polimixina B			C		2 Ampule		Not Reported
	Amikacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18308767	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1829880		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine			S	Unknown	800 Milligram Daily; Started On Hospital Day 6 As A Bridge To Compassionate Use Of Remdesivir; Two D		Teva
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Tocilizumab			S	Unknown	800 Milligram Daily; Given On Hospital Day 7 And 8		Not Reported
	Tocilizumab			S				Not Reported
	Remdesivir			S	Unknown	100 Milligram Daily; Off Label Use Of Remdesivir Started On Hospital Day 10; 100 Mg Daily For Five D		Not Reported
	Vincristine			C	Unknown			Not Reported
	Irinotecan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18334141	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18334476	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Feeling Abnormal; Nausea; Sensory Disturbance; Vomiting	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Enoxaparin			C				Not Reported

		Ergocalciferol			C						Not Reported
		Heparin			C						Not Reported
		Metoclopramide			C						Not Reported
		Ondansetron			C						Not Reported
		Potassium Chloride			C						Not Reported
		Pravastatin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18334481	DIRECT	Y	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir Injection	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18334489	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Diltiazem			C				Not Reported
	Pantoprazole			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Phenylephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18334555	DIRECT	Y	OT			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased; Transaminases Increased	Remdesivir Injection	Y		S	Intravenous (not otherwise specified)	Other Frequency:Event Description;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18334560	DIRECT	Y	OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir Liquid	Y		S	Intravenous (not otherwise specified)	Other Frequency:Event Description;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18334633	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Administration Error; Product Preparation Error; Wrong Schedule	Remdesivir For Injection	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18334733	DIRECT	Y				90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18335073	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Hypertension; Infusion Related Reaction;	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Dexamethasone			C				Not Reported

Pyrexia; Tachycardia; Tachypnoea	Ceftriaxone	C		Not Reported
	Azithromycin	C		Not Reported
	Atorvastatin	C		Not Reported
	Aspirin	C		Not Reported
	Enoxaparin	C		Not Reported
	Ketorolac	C		Not Reported
	Hydrocodone-Acetaminophen	C		Not Reported
	Ondansetron	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18335136	EXPEDITED (15-DAY)		OT	AT-009507513-2009AUT009918		58 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Cancidas			S	Intravenous (not otherwise specified)	1x70mg, Ld (Loading Dose) Continued Because Of Weight		Merck
	Dobutamine			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20mg		Not Reported
	Perlinganit			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Dexdor			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Loading Dose		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd		Not Reported
	Pipitaz			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Baypress			C	Oral	Unk		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk		Not Reported

Catapresan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Vasopressin	C	Intravenous (not otherwise specified)	2iiu/H		Not Reported
Remifentanil Hydrochloride	C	Intravenous (not otherwise specified)	Unk		Not Reported
Blood, Plasma	C	Intravenous (not otherwise specified)	Recovering Plasma		Not Reported
Aquaphoril	C	Oral	Unk		Not Reported
Aquaphoril	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18335143	DIRECT	Y	DE, LT			95 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Creatinine Increased; Pulmonary Oedema; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Vitamin C			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported
	Zinc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18335149	DIRECT	Y	HO			87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S				Not Reported
	Dexamethasone 6 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18335153	DIRECT	Y				68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Dose Omission Issue; Wrong Technique In Product Usage Process	Remdesivir	S	Intravenous drip	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18335159	DIRECT	Y				76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Rash; Respiratory Distress; Somnolence; Therapy Cessation; Troponin Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Insulin Aspart			C				Not Reported
	Insulin Detemir			C				Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18335195	DIRECT	Y	OT			93 YR	Male	ALB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Heart Rate Increased	Remdesivir			S				Gilead
	Melatonin			C				Not Reported
	Midodrine			C				Not Reported
	Miralax			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Sertraline			C				Not Reported
	Systane			C				Not Reported
	Multivitamin			C				Not Reported
	Tamsulosin			C				Not Reported
	Tramadol			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Azithromycin			C				Not Reported
	Buspirone			C				Not Reported
	Dexamethasone			C				Not Reported

	Divalproex Sod Dr	C		Not Reported
	Geodon	C		Not Reported
	Haldol	C		Not Reported
	Levofloxacin	C		Not Reported
	Levothyroxine	C		Not Reported
	Lovenox	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18336572	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0497033		39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18337917	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Administration Error; Product Dispensing Error; Transcription Medication Error	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18337918	DIRECT	Y	HO, OT			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Under Emergency Use Authorization (Eua)			S			5 DAY	Not Reported
	Alfuzosin - Home Med			C				Not Reported
	Aspirin - Home Med			C				Not Reported
	Lipitor - Home Med			C				Not Reported
	Plavix - Home Med			C				Not Reported
	Folic Acid - Home Med			C				Not Reported
	Heparin Sq			C				Not Reported
	Mg Sulfate			C				Not Reported

		Melatonin - Home Med			C					Not Reported
		Toprol Xl - Home Med			C					Not Reported
		Multivitamin - Home Med			C					Not Reported
		Kcl			C					Not Reported
		Seroquel			C					Not Reported
		Flomax			C					Not Reported
		Thiamine - Home Med			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18337919	DIRECT	Y	DE			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Hypernatraemia; Hypertriglyceridaemia; Leukocytosis; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 1000mg Po Once Daily Then Feed Tube Bid			C				Not Reported
	Atorvastatin 40mg Feed Tube At Bedtime			C				Not Reported
	Cefepime 1 Gm Iv Q6hr			C				Not Reported
	Cetriaxone 1 Gm Iv Daily			C				Not Reported
	Cholecalciferol 1000 U Po Once Daily			C				Not Reported
	Dexamethasone 6mg Iv Once Daily			C				Not Reported
	Enoxaparin 90mg Sq Q12hr, 40mg Sq At Bedtime X4days, Then 90mg Sq Q12h			C				Not Reported
	Enoxaparin 50mg Sq Q12hr			C				Not Reported
	Famotidine 20mg Feed Tube Daily X26days, Iv Daily X9days, Then Po Bid			C				Not Reported
	Fluconazole 150mg Po Daily X3days, 400mg Iv Once, 200mg Iv Daily X3day			C				Not Reported
	Fluconazole 200mg Po Daily			C				Not Reported
	Hydroxychloroquine 400mg Po Q12hr			C				Not Reported
	Meropenem Renally Dosed Iv			C				Not Reported
	Methylprednisolone 40mg Iv Q8hr			C				Not Reported

	Sulfamethoxazole/Trimethoprim 800/160mg Po Once Daily	C	Not Reported
	Vancomycin Iv Per Protocol	C	Not Reported
	Zinc Sulfate 220mg Feed Tube Daily X5days Then Po Daily X8days	C	Not Reported
	Convalescent Plasma 07/03, 07/06	C	Not Reported
	Tocilizumab Iv Once	C	Not Reported
	Insulin Glargine/Lispro	C	Not Reported
	Melatonin 9mg Po Qhs	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18337921	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Increased; Hypotension; Oxygen Saturation Decreased; Pneumonia; Thrombocytopenia	Remdesivir Eua			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18337922	DIRECT	Y	HO			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bradycardia; Cardio-Respiratory Arrest	Remdesivir Injection (Iyophilized Powder)	Y		S	Intravenous (not otherwise specified)			Gilead
	Amiodarone Injectable			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18337965	DIRECT	Y	OT			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18338010	DIRECT	Y	HO			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Aspiration; Foetal Exposure During Pregnancy; Maternal Exposure During Pregnancy; Procedural Haemorrhage; Respiratory Disorder	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18338980	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Heart Rate Increased; Hypoxia; Sepsis; Sinus Bradycardia	Remdesivir			S				Not Reported
	Anutruotyline			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Symbicort			C				Not Reported
	Colecaciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Fluoxetine			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Glarfine			C				Not Reported
	Insulin Iosphane			C				Not Reported
	Insulin Lispro Slding Scale			C				Not Reported

	Lurasidone			C						Not Reported
	Pantoprazole			C						Not Reported
	Pregabalin			C						Not Reported
	Thiamine			C						Not Reported
	Trazodone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18338985	DIRECT	Y				26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported
	Lr			C				Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C				Not Reported
	Trimethoprim/Sulfamethoxazole			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18359475	DIRECT		DE			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Maternal Condition Affecting Foetus; Off Label Use; Peritoneal Dialysis; Premature Labour; Vertical Infection Transmission	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Amikacin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18359779	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Multiple Organ Dysfunction Syndrome;	Remdesivir			S				Not Reported

Sepsis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18359783	DIRECT					60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Remdesivir			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Other Dose:0.8mg/Kg;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2020	18364657	DIRECT					40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Product Use In Unapproved Indication; Transaminases Increased; Transfusion	Remdesivir			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Other Route:Iv	9 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18208723	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0492452		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Solu-Medrol			C	Intravenous (not otherwise specified)	80 Mg		Not Reported
	Atorvastatin			C	Oral	10 Mg		Not Reported

			Lovenox [Enoxaparin Sodium]		C	Subcutaneous	30 Mg		Not Reported
			Gabapentin		C	Oral	600 Mg		Not Reported
			Novolog		C	Subcutaneous	Unk		Not Reported
			Lantus		C	Subcutaneous	Unk		Not Reported
			Plasma		C		Unk		Not Reported
			Interleukin-6		C				Not Reported
			Tenofovir		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18219744	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0492866		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amiodarone			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Quetiapine			C				Not Reported
	Ramelteon			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported
	Oxygen			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Metoprolol			C				Not Reported
	Prostacyclin			C				Not Reported
	Plasma			C				Not Reported
	Peridex [Chlorhexidine Gluconate]			C				Not Reported

		Fluticasone			C					Not Reported
		Insulin Lispro			C					Not Reported
		Lactated Ringers			C					Not Reported
		Multivitamins [Vitamins Nos]			C					Not Reported
		Thiamine			C					Not Reported
		Bisacodyl			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18250001	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0494245		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Achromobacter Infection; Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cor Pulmonale; Death; Disease Progression; Endotracheal Intubation Complication; Fluid Overload; Hypernatraemia; Pneumonia Bacterial; Pulmonary Oedema; Sepsis; Supraventricular Tachycardia	Remdesivir			S	Unknown	Unk		Gilead
	Dexamethasone			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18280617	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0495313		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bradycardia; Hypoxia; Inflammatory Marker Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Atorvastatin			C	Oral	80 Mg		Not Reported

Ceftriaxone	C	Intravenous (not otherwise specified)	1 G		Not Reported
Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
Enoxaparin	C	Subcutaneous	70 Mg		Not Reported
Ergocalciferol	C		50000 Unit		Not Reported
Guaifenesin	C	Oral	10 Ml, Q6h		Not Reported
Ipratropium/Albuterol	C	Respiratory (inhalation)	3 Ml, Qid		Not Reported
Latanoprost	C		1 Dosage Form		Not Reported
Ondansetron	C	Intravenous (not otherwise specified)	4 Mg, Q6h		Not Reported
Zinc Sulfate	C	Oral	220 Mg, Qd		Not Reported
Azithromycin	C	Intravenous (not otherwise specified)	500 Mg		Not Reported
Famotidine	C	Intravenous (not otherwise specified)	20 Mg, Bid		Not Reported
Docusate	C	Oral	100 Mg, Bid		Not Reported
Dorzolamide	C		Unk		Not Reported
Metoprolol Succinate	C	Oral	12.5 Mg, Qd		Not Reported
Metoprolol Succinate	C		25 Unk		Not Reported
Timolol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18314522	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0496388		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Covid-19; General Physical Health Deterioration; Hepatotoxicity; Hypotension;	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amiodarone			C	Intravenous (not	100mg, 100mg, 250mg		Not Reported

Hypovolaemia; Hypoxia; Multiple Organ Dysfunction Syndrome; Thrombosis			otherwise specified)			
	Atorvastatin	C	Oral	10 Mg		Not Reported
	Albumin	C				Not Reported
	Ativan	C				Not Reported
	Avapro	C				Not Reported
	Acetaminophen	C				Not Reported
	Ascorbic Acid	C				Not Reported
	Azithromycin	C				Not Reported
	Ceftriaxone	C				Not Reported
	Cefepime	C				Not Reported
	Nimbex [Nimesulide]	C				Not Reported
	Lovenox [Enoxaparin Sodium]	C				Not Reported
	Dexamethasone	C				Not Reported
	Dextrose	C				Not Reported
	Pepcid [Famotidine]	C				Not Reported
	Fentanyl	C				Not Reported
	Glucagon	C				Not Reported
	Glucose	C				Not Reported
	Guaifenesin/Codeine	C				Not Reported
	Haldol [Haloperidol]	C				Not Reported
	Imdur	C				Not Reported
	Novolin R	C				Not Reported
	Labetalol	C				Not Reported
	Metformin	C				Not Reported
	Versed	C				Not Reported
	Morphine	C				Not Reported
	Levophed	C				Not Reported
	Protonix [Omeprazole]	C				Not Reported
	Phenylephrine	C				Not Reported
	Propofol	C				Not Reported
	Rocuronium	C				Not Reported
	Senna [Sennoside A+B]	C				Not Reported
	Sodium Bicarbonate	C				Not Reported
	Zinc	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18338793	DIRECT	Y	DE			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Acute Respiratory Distress Syndrome; Bacterial Infection	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead
	Amiodarone Iv X2 Days Then 200mg Bid Feed Tube		C		Not Reported
	Ascorbic Acid 500mg Po Tid		C		Not Reported
	Azithromycin 500mg Iv Daily		C		Not Reported
	Cefepime 1 Gm Iv Q8hr X 7 Days Then Q12hr		C		Not Reported
	Ceftriaxone 1 Gm Iv Once Daily		C		Not Reported
	Cholecalciferol 2000 Units Po Daily		C		Not Reported
	Dexamethasone 6mg Iv Once Daily		C		Not Reported
	Dexamethasone 6mg Iv Once Daily		C		Not Reported
	Enoxaparin 40mg Sq Q12hr		C		Not Reported
	Famotidine 20mg Po Q12hr X6 Days Then 20mg Po Daily		C		Not Reported
	Melatonin 6mg Po Qhs		C		Not Reported
	Meropenem 1gm Iv Daily		C		Not Reported
	Micafungin 100mg Iv Daily		C		Not Reported
	Pantoprazole 40mg Iv Daily X2 Days Then 40mg Iv Q12hr		C		Not Reported
	Vancomycin Per Protocol		C		Not Reported
	Zinc 220mg Po Daily		C		Not Reported
	Heparin		C		Not Reported
	Insulin Glargine/Lispro		C		Not Reported
	Thiamine 100mg Po Bid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18338798	DIRECT					39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18338871	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2020M1082827			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombophlebitis; Transaminases Increased	Paracetamol			S	Unknown	1 Gram, Qid (1 G, Qid)		Mylan
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram, Total (200 Mg, Once)		Mylan
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd		Mylan
	Nutriflex /07403401/			S	Parenteral	Unk		Mylan
	Cefotaxim			S	Intravenous (not otherwise specified)	1 Gram, Tid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18339072	DIRECT	Y	HO			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Expired Product Administered; Product Dose Omission Issue; Product Storage Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 4mg Tablet (6mg Dose)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18339092	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0497197		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Cardiac Failure; Death; Hyponatraemia; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Myocarditis	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported

	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	2 G, Qd	Not Reported
	Clopidogrel	C	Oral	75 Mg	Not Reported
	Amiodarone	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Asa	C		325 Mg, Once	Not Reported
	Asa	C	Oral	81 Mg	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	1 G, Q8h	Not Reported
	Enoxaparin	C		150 Mg	Not Reported
	Enoxaparin	C	Subcutaneous	200 Mg, Bid	Not Reported
	Famotidine	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
	Gabapentin	C	Oral	600 Mg, Bid	Not Reported
	Meropenem	C	Intravenous (not otherwise specified)	500 Mg, Bid	Not Reported
	Micafungin	C	Intravenous (not otherwise specified)	100 Mg, Qd	Not Reported
	Vancomycin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18339328	DIRECT	Y	OT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatotoxicity	Remdesivir (Veklury)	Y		S	Intravenous drip			Not Reported
	Acetaminophen (On As Needed Basis)			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin-Codeine (On As			C				Not Reported

Needed Basis)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18339329	DIRECT	Y	OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Hypersensitivity; Rash	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18339351	DIRECT	Y				91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once, 100mg Qd;		Gilead
	Remdesivir 200mg/250ml Ns			C				Not Reported
	Remdesivir 100mg/250ml Ns			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18340310	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0497194		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Premature Rupture Of Membranes	Remdesivir			S	Unknown	Unk		Gilead
	Hydroxychloroquine			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Heparin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Betamethasone			C				Not Reported
	Oxygen			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18340427	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497145		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Arrest; Covid-19 Pneumonia; Death; Fungaemia; Hyponatraemia; Hypovolaemic Shock; Pneumothorax; Septic Shock; Supraventricular Tachycardia; Type 2 Diabetes Mellitus	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C	Oral	1000 Mg, Tid		Not Reported
	Azithromycin			C	Oral	500 Mg, Qd		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	1 G, Q6h		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	10 Mg, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6mg, 10mg, Once Daily		Not Reported
	Meropenem			C		Unk		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported
	Zinc Sulphate			C	Oral	220 Mg, Bid		Not Reported
	Vancomycin			C		Unk		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	1500 Mg, Once		Not Reported
	Micafungin			C	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Micafungin			C	Intravenous (not otherwise specified)	100 Unk		Not Reported
	Famotidine			C	Oral	20 Mg Q12h		Not Reported
	Plasma			C		Unk		Not Reported
	Enoxaparin			C	Subcutaneous	70 Mg, Q12h		Not Reported

	Enoxaparin			C	Subcutaneous	40 Mg, Qd			Not Reported
	Enoxaparin			C	Subcutaneous	60 Mg Q12h			Not Reported
	Methylprednisolone			C		Unk			Not Reported
	Glucophage [Metformin]			C	Oral	200 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18342802	DIRECT	Y				52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18342826	DIRECT	Y	OT			93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous bolus		5 DAY	Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18342832	DIRECT	Y	DE			86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Pulseless Electrical Activity	Remdesivir			S	Intravenous bolus			Gilead
	Enoxaparin 0.5 Mg/Kg Sq Q 12h			C				Not Reported
	Methylprednisolone 50 Mg Q 12 H			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18342846	DIRECT		HO, OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test	Remdesivir	S		Gilead
Increased	Remdesivir	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18342872	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S				Gilead
	Acetaminophen 325mg Tablets			C				Not Reported
	Azithromycin 500mg Injectable			C				Not Reported
	Azithromycin 250mg Tablets			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Ceftriaxone 1gm Injectable			C				Not Reported
	Dexamethasone Injectable			C				Not Reported
	Dexmedetomidine Injectable			C				Not Reported
	Enoxaparin Injectable			C				Not Reported
	Famotidine Injectable			C				Not Reported
	Furosemide Injectable			C				Not Reported
	Propofol Injectable			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2020	18342913	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2020	18342836	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Infusion Related Reaction; Therapy Cessation	Remdesivir Powder For Reconstitution			S	Intravenous (not otherwise specified)			Gilead

	Dexamethasone Inj (6 Mg Daily)			C					Not Reported
	Cisatracurium 100 Mg/100 Ml Ns Drip			C					Not Reported
	Fentanyl 1000 Mcg/100 Ml Ns Drip			C					Not Reported
	Insulin Regular 100 Unit/100 Ml Ns Drip			C					Not Reported
	Midazolam 50 Mg/50 Ml Ns Drip			C					Not Reported
	Levofloxacin 750 Mg/150 Ml Daily			C					Not Reported
	Pantoprazole 40 Mg Iv Daily			C					Not Reported
	Heparin 25000/250 Ml D5w Drip			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2020	18342841	DIRECT	Y	LT			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Carbidopa-Levodopa			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Diltiazem			C				Not Reported
	Guaifenesin			C				Not Reported
	Hydralazine			C				Not Reported
	Montelukast			C				Not Reported
	Rasagiline			C				Not Reported
	Tamsulosin			C				Not Reported
	Trospium			C				Not Reported
	Methylprednisolone			C				Not Reported
	Metoprolol			C				Not Reported
	Zosyn			C				Not Reported
	Tiotropium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18299246	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0495913		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure;	Remdesivir			S	Intravenous (not	200 Mg, Once		Gilead

Acute Kidney Injury; Multi-Organ Disorder; Respiratory Distress			otherwise specified)		
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Plasma	C	Intravenous (not otherwise specified)	1 Unit	Not Reported
	Atorvastatin	C	Oral	40 Mg	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
	Enoxaparin	C	Subcutaneous	60 Mg, Bid	Not Reported
	Pantoprazole	C		40 Mg, Qd	Not Reported
	Apixaban	C			Not Reported
	Heparin	C	Intravenous (not otherwise specified)	1.79 U/Kg/Hr	Not Reported
	Angiotensin Ii	C	Intravenous (not otherwise specified)	40 Ng/Kg/Min	Not Reported
	Insulin	C	Subcutaneous	15 Units	Not Reported
	Hydromorphone	C	Intravenous (not otherwise specified)	0.6 Mg/Hr	Not Reported
	Hydromorphone	C			Not Reported
	Propofol	C	Intravenous (not otherwise specified)	5mcg/Kg/Min	Not Reported
	Propofol	C			Not Reported
	Norepinephrine	C	Intravenous (not otherwise specified)	50mcg/Min	Not Reported
	Ceftriaxone	C		2 G	Not Reported
	Sevelamer	C		1.6 G	Not Reported
	Polyethylene Glycol [Macrogol]	C	Oral	17 G	Not Reported
	Senna Acutifolia	C	Oral	176mg/ 5ml	Not Reported
	Vasopressin	C	Intravenous (not otherwise specified)	0.04 U	Not Reported
	Calcium Gluconate	C	Intravenous (not otherwise specified)	2 G	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18311124	EXPEDITED (15-DAY)		DE, LT	BR-ROCHE-2681847		66 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Septic Shock	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	As Per Protocol (Loading Dose (Patients Will Subsequently Be Administered A 100 Mg Once-Daily Iv Mai		Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Oseltamivir			C				Not Reported
	Enalapril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18343981	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18344016	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18344017	DIRECT	Y				90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18344019	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	5 DAY	Gilead
	Memantine			C				Not Reported
	Olanzapine			C				Not Reported
	Tamsulosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18344131	DIRECT	Y	HO			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Mechanical Vent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18344227	DIRECT	Y	OT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported

	Guaifenesin			C						Not Reported
	Metformin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18344486	DIRECT	Y				84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Zosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18344542	DIRECT	Y	OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18344689	DIRECT	Y	DE			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Sounds Abnormal; Respiratory Arrest	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18344690	DIRECT	Y	OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18345674	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0497291		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Propofol			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Midazolam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18346904	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497321		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Death; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C	Oral	1000 Mg, Qd		Not Reported
	Atorvastatin			C		40 Mg Feed Tube At Bedtime		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	1 G, Q6h		Not Reported
	Cholecalciferol			C	Oral	1000 Units		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Fluconazole			C		Unk		Not Reported

Fluconazole	C		Unk	Not Reported
Hydroxychloroquine	C	Oral	400 Mg Q12h	Not Reported
Meropenem	C	Intravenous (not otherwise specified)	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	40 Mg, Q8h	Not Reported
Sulphamethoxazole + Trimethoprim	C	Oral	800 / 160 Mg	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	Unk	Not Reported
Zinc Sulphate	C		Unk	Not Reported
Plasma	C		Unk	Not Reported
Tocilizumab	C		Unk	Not Reported
Insulin Glargine	C		Unk	Not Reported
Melatonin	C	Oral	9 Mg, Qhs	Not Reported
Levophed	C			Not Reported
Vasopressin	C			Not Reported
Epinephrine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18347767	DIRECT	Y				72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress	Remdesivir			S				Not Reported
Syndrome; Alanine	Acetaminophen			C				Not Reported
Aminotransferase	Ergocalciferol			C				Not Reported
Increased; Aspartate	Ipratropium/Albuterol			C				Not Reported
Aminotransferase	Latanoprost			C				Not Reported
Increased; Blood Calcium	Ondansetron			C				Not Reported
Decreased; Bradycardia;	Zinc Sulfate			C				Not Reported
Chest Pain; Dizziness;	Atorvastatin			C				Not Reported
Heart Rate Increased;	Azithromycin			C				Not Reported
Inflammatory Marker	Ceftriaxone			C				Not Reported
Increased; Nausea;	Dexamethasone			C				Not Reported
Oxygen Saturation	Docusate			C				Not Reported
Decreased; Respiratory	Dorzolamide			C				Not Reported

Distress; Sensation Of Foreign Body; Sinus Arrest	Enoxaparin			C					Not Reported
	Famotidine			C					Not Reported
	Metoprolol Succinate			C					Not Reported
	Timolol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18347769	DIRECT	Y				79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18347823	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported
	Metoprolol Xl			C				Not Reported
	Enoxaparin			C				Not Reported
	Losartan			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Guaifenesin/Codeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18348119	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:1x Only;		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetazolamide Injection			C				Not Reported
	Dexamethasone Injection			C				Not Reported

	Furosemide Injection	C		Not Reported
	Calcium Gluconate Iv	C		Not Reported
	Potassium Bicarb-Citric Acid Tablet	C		Not Reported
	Acetaminophen Tablet	C		Not Reported
	Enoxaprin Injection	C		Not Reported
	Fentanyl Infusion	C		Not Reported
	Insulin Lispro	C		Not Reported
	Metolazone Tablet	C		Not Reported
	Midazolam Infusion	C		Not Reported
	Odansetron Tablet	C		Not Reported
	Pantoprazole Injection	C		Not Reported
	Propofol Infusion	C		Not Reported
	Rocuronium Infusion	C		Not Reported
	Potassium Chloride Iv	C		Not Reported
	Potassium Chloride Iv	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2020	18348136	DIRECT	Y	OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Urticaria	Remdesivir	Y		S				Gilead
	Benzonatate (Tessalon Perles) Capsule 100 Mg			C				Not Reported
	Dexamethasone (Decadron Tablet 6 Mg			C				Not Reported
	Enoxaparin (Lovenox) (Conc: 40 Mg/ 0.4 Ml) Injection 40 Mg			C				Not Reported
	Guaifenesin 12 Hr (Mucinex) Er Tablet (Do Not Crush/Chew) 1,200 Mg			C				Not Reported
	Pantoprazole (Protonix) Dr Tablet (Do Not Crush/Chew) 40 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18255479	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0494345		86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Failure; Covid-19	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone	C				Not Reported
	Cefepime	C				Not Reported
	Vancomycin	C				Not Reported
	Quetiapine	C				Not Reported
	Allopurinol	C				Not Reported
	Escitalopram	C				Not Reported
	Famotidine	C				Not Reported
	Heparin	C				Not Reported
	Levothyroxine	C				Not Reported
	Fentanyl	C				Not Reported
	Norepinephrine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18348808	DIRECT	Y	OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Rash Erythematous; Rash Pruritic	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18349565	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Not Reported
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Guaifenesin Er			C				Not Reported
	Levothyroxine			C				Not Reported
	Azithromycin			C				Not Reported
	Carvedilol			C				Not Reported
	Docusate			C				Not Reported
	Gabapentin			C				Not Reported
	Nortriptyline			C				Not Reported
	Sacubitril/Valsartan			C				Not Reported
	Spironolactone			C				Not Reported

	Zolpidem Tartrate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18349570	DIRECT	Y				77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Dexamthasone			C				Not Reported
	Furosemide			C				Not Reported
	Meclizine			C				Not Reported
	Valsartan			C				Not Reported
	Hydralazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18349688	DIRECT	Y	DE			88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18349856	DIRECT	Y				20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen 325mg Tablets Prn			C				Not Reported
	Albuteral Mdi			C				Not Reported
	Atorvastatin 10mg Tablet			C				Not Reported
	Azithromycin 500mg Ivpb			C				Not Reported
	Azithromycin 250mg Tablet			C				Not Reported

	Ceftriaxone 1 G Ivpb	C	Not Reported
	Cefuroxime 500mg Tablet	C	Not Reported
	Enoxaparin 40mg Inj	C	Not Reported
	Novolog Flexpen	C	Not Reported
	Humalog Kwikpen	C	Not Reported
	Levemir Flextouch	C	Not Reported
	Ketoroloc 30mg Inj Prn	C	Not Reported
	Lactobacillus Cap Tid	C	Not Reported
	Lorazepam 1mg Prn	C	Not Reported
	Methylprednisolone 40mg Ivp	C	Not Reported
	Prednisone 20mg Tablet	C	Not Reported
	Tramadol 50mg Tablet Prn	C	Not Reported
	Trazadone 50mg Tablet	C	Not Reported
	Magnesium 4 G Ivpb X1	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18349968	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; General Physical Health Deterioration; Oxygen Saturation Decreased; Sepsis; Shock	Remdesivir			S				Not Reported
	Decadron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18349970	DIRECT	Y	DE			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Covid-19 Pneumonia; Fibrin D Dimer Increased; Pulseless Electrical Activity; Transfusion	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18349975	DIRECT	Y	DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blood Culture Positive; Covid-19 Pneumonia; False Positive Investigation Result; Laboratory Test Interference; Streptococcal Infection; Superinfection; Transfusion	Remdesivir			S				Not Reported
	Decadron			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18349999	EXPEDITED (15-DAY)			US-GILEAD-2020-0497561			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18350470	EXPEDITED (15-DAY)		DE, HO, OT	US-SA-2020SA271806			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sitagliptin			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Sodium Chloride			C		Unk		Not Reported
	Insulin Human;Insulin Human Injection, Isophane			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Fenofibrate			C		Unk		Not Reported

	Heparin			C		Unk				Not Reported
	Methylprednisolone			C		Unk				Not Reported
	Nph Insulin			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18352297	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0497511		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amiodarone			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Melatonin			C				Not Reported
	Meropenem			C				Not Reported
	Micafungin			C				Not Reported
	Pantoprazole			C				Not Reported
	Vancomycin			C				Not Reported
	Zinc			C				Not Reported
	Heparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Thiamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354017	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0497579		93 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Buspirone			C				Not Reported

			Dexamethasone		C				Not Reported
			Divalproex		C				Not Reported
			Geodon [Ziprasidone Hydrochloride]		C				Not Reported
			Haldol [Haloperidol]		C				Not Reported
			Levofloxacin		C				Not Reported
			Levothyroxine		C				Not Reported
			Lovenox [Enoxaparin Sodium]		C				Not Reported
			Melatonin		C				Not Reported
			Midodrine		C				Not Reported
			Miralax		C				Not Reported
			Ondansetron		C				Not Reported
			Pantoprazole		C				Not Reported
			Sertraline		C				Not Reported
			Systane		C				Not Reported
			Multivitamin [Vitamins Nos]		C				Not Reported
			Tamsulosin		C				Not Reported
			Tramadol		C				Not Reported
			Zinc Gluconate		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354032	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metabolic Encephalopathy	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354038	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354040	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death	Remdesivir			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354045	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S				Not Reported
	Fentanyl			C				Not Reported
	Lorazepam			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354058	DIRECT	Y	DE			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Cardiac Event; Acute Kidney Injury; Blood Creatine Increased; Blood Glucose Increased; Blood Lactic Acid Increased; Blood Magnesium Increased; Blood Phosphorus Increased; Blood Potassium Increased; Blood Urea Increased; Carbon Dioxide Decreased; Depression; Haemodialysis; Hyperkalaemia; Hyperlipidaemia; Hypertension; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500mg Iv Once And 500mg Po Once			C				Not Reported
	Cefepime 1gm Iv Q8hr X2 Days Then 1gm Iv Q6hr			C				Not Reported
	Ceftriaxone 1gm Iv Once			C				Not Reported
	Dexamethasone 10mg Daily Iv			C				Not Reported
	Dexamethasone 10mg Daily Iv			C				Not Reported
	Enoxaparin 60mg Sq Q12hr			C				Not Reported
	Famotidine 20mg Iv Bid X11 Days Then 20mg Po Bid X6 Days Then Iv			C				Not Reported
	Hydroxychloroquine 400mg Po Q12hr X1 Day, Then 400mg Po Daily			C				Not Reported
	Melatonin 9mg Po Qhs			C				Not Reported
	Meropenem 1 Gm Iv Q8hr			C				Not Reported
	Prednisone 20mg Po Once			C				Not Reported
	Vancomycin Per Protocol			C				Not Reported
	Vancomycin 2000mg Iv Once			C				Not Reported
	Zinc Sulfate 220mg Po Once			C				Not Reported

		Daily								
		Insulin Glargine/Lispro/Regular		C						Not Reported
		Convalescent Plasma		C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354063	DIRECT	Y	DE			52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anisocytosis; Bacteraemia; Cardiac Arrest; Haemodialysis; Hyperglycaemia; Hypotension; Macrocytosis; Microcytosis; Platelet Morphology Abnormal; Polychromasia; Procalcitonin Increased; Pulseless Electrical Activity; Red Blood Cell Nucleated Morphology; Renal Failure; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500mg Iv Daily			C				Not Reported
	Cefepime 1gm Iv Q12hr X2 Days Then 1gm Iv Q8hr			C				Not Reported
	Ceftriaxone 1gm Iv Once			C				Not Reported
	Daptomycin 500mg Iv Daily X2 Days Then 500mg Iv Q48h			C				Not Reported
	Dexamethasone 10mg Daily Iv			C				Not Reported
	Famotidine 20mg Iv Q12hr X11 Days Then 20mg Iv Daily			C				Not Reported
	Fluconazole 400mg Iv Q2h X2 Times Then 200mg Iv Daily			C				Not Reported
	Insulin Glargine/Lispro/Regular			C				Not Reported
	Meropenem 0.5gm Iv Q8hr			C				Not Reported
	Metronidazole 500mg Iv Q8hr			C				Not Reported
	Micafungin 100mg Iv Daily			C				Not Reported
	Vancomycin Iv Per Protocol			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354074	DIRECT	Y	DE			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Glucose	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Zinc Sulfate 220mg Po Bid			C				Not Reported
	Vancomycin Per Protocol			C				Not Reported
	Ascorbic Acid 1000mg Po Q12hr			C				Not Reported

Increased; Blood Lactate Dehydrogenase Increased; Blood Magnesium Increased; Blood Potassium Increased; Cardiac Arrest; Haemodialysis; Haemoglobin Decreased; Hypoxia; Platelet Count Decreased; Red Blood Cell Count Decreased; White Blood Cell Count Increased	Azithromycin 500mg Iv Once Then 500mg Po Daily			C					Not Reported
	Cefepime 1gm Iv Q6hr			C					Not Reported
	Dexamethasone 20mg Iv Daily X3 Days Then 10mg Iv Daily			C					Not Reported
	Enoxaparin 40mg Sq X1day, 60mg Sq Bid X2day, Then 100mg Sq Bid			C					Not Reported
	Famotidine 20mg Feed Tube Daily			C					Not Reported
	Insulin Glargine/Lispro/Regular			C					Not Reported
	Meropenem 1 Gm Iv Daily Once Then 0.5gm Iv Q6hr			C					Not Reported
	Covalescent Plasma			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354087	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354088	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0497350		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chills; Disturbance In Attention; Hyperhidrosis; Hypertension; Hypoaesthesia; Nervousness; Paraesthesia; Peripheral Swelling; Rash; Rash; Rash; Rash; Rash; Tremor	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354095	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354102	DIRECT	Y	OT			90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354108	DIRECT	Y	DE			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hyperkalaemia; Pneumonia; Renal Tubular Necrosis; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Cefepime 1gm Iv Q8hr			C				Not Reported
	Ceftolozane/Tazobactam 3gm Iv Q8hr			C				Not Reported
	Dexamethasone 20mg Iv Daily			C				Not Reported
	Dexamethasone 20mg Iv Dai10			C				Not Reported
	Enoxaparin 40mg Sq Once Then 80mg Sq Bid			C				Not Reported
	Famotidine 20mg Iv Bid X3 Days Then 20mg Iv Daily/Bid			C				Not Reported
	Meropenem 0.5gm Iv Once Then Q8hr			C				Not Reported
	Methylprednisolone 40mg Iv Q6hr X2days Then 40mg Iv Q12hr			C				Not Reported
	Metronidazole 500mg Iv Q8hr			C				Not Reported
	Pantoprazole 40mg Iv Bid			C				Not Reported

		Piperacillin/Tazobactam 3.375 gm Iv Q8hr			C					Not Reported
		Vancomycin Iv Per Protocol			C					Not Reported
		Vancomycin 500mg Feed Tube Q6hr			C					Not Reported
		Zinc Sulfate 220mg Feed Tube Once Daily			C					Not Reported
		Insulin Glargine/Lispro/Regular			C					Not Reported
		Convalescent Plasma			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354126	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354134	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354142	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354150	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354157	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354163	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354165	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354169	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354175	DIRECT		DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18354182	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Disease Complication	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2020	18355280	DIRECT	Y	HO			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Decreased	Remdesivir 100mg Iv			S	Intravenous (not otherwise specified)	Other Frequency:Day #1;		Gilead
	Remdesivir 100mg Iv			S	Intravenous (not otherwise specified)	Other Frequency:Day 2-5;		Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18280095	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0495305		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Qd		Gilead
	Albumin			C		Unk		Not Reported
	Amiodarone			C	Oral	400		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fludrocortisone			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported

	Haloperidol	C		Unk	Not Reported
	Insulin Glargine	C		Unk	Not Reported
	Insulin Lispro	C		Unk	Not Reported
	Iopamidol	C		Unk	Not Reported
	Bio K Plus	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Metoclopramide	C		Unk	Not Reported
	Midodrine	C		Unk	Not Reported
	Multivitamin [Vitamins Nos]	C		Unk	Not Reported
	Piperacillin/Tazobactam	C		Unk	Not Reported
	Potassium Chloride	C		Unk	Not Reported
	Potassium Phosphates	C		Unk	Not Reported
	Vancomycin	C		Unk	Not Reported
	Acetaminophen	C	Oral	650 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18354698	DIRECT	Y	DE			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Band Neutrophil Count Increased; Basophil Percentage Increased; Bilirubin Conjugated Increased; Blood Albumin Decreased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Phosphorus Decreased; Chronic	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 1gm Iv Daily			C				Not Reported
	Dexamethasone 10mg Iv Daily			C				Not Reported
	Enoxaparin 70mg Sq Bid			C				Not Reported
	Famotidine 20mg Feed Tube Bid X18 Days Then 20mg Iv Bid			C				Not Reported
	Hydroxychloroquine 400mg Po Q12hr X2 Days Then 400mg Po Daily			C				Not Reported
	Insulin Glargine/Lispro			C				Not Reported
	Melatonin 6mg Po Qhs			C				Not Reported
	Methylprednisone 60mg Iv Q6hr			C				Not Reported
	Piperacillin/Tazobactam 3.375			C				Not Reported

Kidney Disease; Eosinophil Count Decreased; Eosinophil Percentage Decreased; Fibrin D Dimer Increased; Haematocrit Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Lymphocyte Percentage Decreased; Mean Cell Haemoglobin Increased; Mean Cell Volume Increased; Metabolic Acidosis; Monocyte Count Decreased; Monocyte Percentage Decreased; Neutrophil Count Increased; Platelet Morphology Abnormal; Procalcitonin Increased; Protein Total Decreased; Red Blood Cell Count Decreased; Red Blood Cell Nucleated Morphology Present; Respiratory Acidosis; Respiratory Failure; Serum Ferritin Increased; White Blood Cell Count Decreased	gm Iv Q6hr		
	Vancomycin 1750mg Iv Once	C	Not Reported
	Zinc Sulfate 220mg Feed Tube Daily	C	Not Reported
	Convalescent Plasma	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18355588	DIRECT	Y				81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Dispensing Error; Product Preparation Error	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18355592	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18355626	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous bolus			Gilead
	Tocilizumab			C				Not Reported
	Albuterol			C				Not Reported
	Atropine			C				Not Reported
	Azithromycin			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18355715	DIRECT	Y	CA, DE, OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; General Physical Health Deterioration; Liver Function Test Increased; Maternal Exposure During Pregnancy	Remdesivir	Y		S			4 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18355780	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18356001	EXPEDITED (15-DAY)			US-GILEAD-2020-0497664			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Other	100 Mg, Through A Pneumatic Tube System For Delivery		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18356773	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0497744		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Liver Function Test Abnormal; Renal Failure	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous bolus	100 Unk		Gilead
	Simvastatin			C		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18356819	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0497730		31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Remdesivir			S	Unknown	Unk		Gilead
	Lovenox [Enoxaparin Sodium]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18358913	DIRECT	Y	HO			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous drip			Gilead
	Methylprednisolone			C				Not Reported
	Montelukast			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Trazodone			C				Not Reported
	Azithromycin			C				Not Reported
	Tocilizumab			C				Not Reported
	Ranolazine Xr			C				Not Reported
	Pravastatin			C				Not Reported
	Metoprolol			C				Not Reported
	Lisinopril			C				Not Reported
	Levothyroxine			C				Not Reported
	Gabapentin			C				Not Reported
	Clopidogrel			C				Not Reported
	Aspirin			C				Not Reported
	Enoxaparin			C				Not Reported
	Propofol			C				Not Reported
	Midazolam			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18358919	DIRECT	Y				14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue	Remdesivir Eua			S	Intravenous bolus	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18358945	DIRECT	Y	DE			91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Death	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18358949	DIRECT	Y	OT			92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Sinus Node Dysfunction	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported
	Albuterol			C				Not Reported
	Heparin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxoparin			C				Not Reported
	Hyoscyamine			C				Not Reported
	Insulin Detemir			C				Not Reported
	Insulin Aspart			C				Not Reported
	Melatonin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Amlodipine			C				Not Reported
	Famotadine			C				Not Reported
	Levothyroxine			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Diclofenac Topical			C				Not Reported
	Folic Acid			C				Not Reported
	Losartan			C				Not Reported
	Vancomycin			C				Not Reported
	Senna			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18358965	DIRECT	Y	DS			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Permanent; Deafness Unilateral; Tinnitus	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Eliquis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2020	18359303	DIRECT					49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Extravasation; Irritability; Pruritus; Swelling	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18082610	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486085		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endotracheal Intubation; Foetal Death; Maternal Exposure During Pregnancy	Remdesivir			S	Unknown	Unk		Gilead
	Heparin			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Lovenox [Levofloxacin]			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Nimbex [Nimesulide]			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Precedex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18163607	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0490646		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tylenol	C				Not Reported
	Albuterol [Salbutamol]	C				Not Reported
	Amlodipine	C				Not Reported
	Aspirin 81	C				Not Reported
	Clopidogrel	C				Not Reported
	Dexamethasone	C				Not Reported
	Guanfacine	C				Not Reported
	Ipratropium Bromide	C				Not Reported
	Lisinopril	C				Not Reported
	Tamsulosin	C				Not Reported
	Metoprolol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18179218	EXPEDITED (15-DAY)			US-GILEAD-2020-0490669		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Dexamethasone			C				Not Reported
	Pantoprazole			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Benzonatate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18304128	EXPEDITED (15-DAY)			DK-BAUSCH-BL-2020-026864			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased;	Dexamethasone			S	Intravenous (not			Bausch And Lomb

Glycosylated Haemoglobin Increased					otherwise specified)				
	Veklury			S	Intravenous (not otherwise specified)				Not Reported
	Veklury			S	Intravenous (not otherwise specified)				Not Reported
	Cetirizin			C					Not Reported
	Sumatriptan			C					Not Reported
	Mometasone			C					Not Reported
	Hydrocortisone Butyrate			C					Not Reported
	Candesartan Cilexetil			C					Not Reported
	Metformine (Metformin)			C					Not Reported
	Pantoprazole			C					Not Reported
	Betamethasone			C					Not Reported
	Levothyroxine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18358791	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-051463		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Ceftriaxone			S	Intravenous (not otherwise specified)	100 Milliliter, Once A Day		Aurobindo
	Enoxaparine			S	Subcutaneous	1000 International Unit, Two Times A Day		Not Reported
	Ivermectine			S	Oral	18 Milligram, Once A Day		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Aurobindo
	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo
	Dexamethasone			S	Intramuscular	6 Milligram, Once A Day		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200mg On D1 Then 100mg D2 To D5		Not Reported
	Diffu K			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Oxygen			C	Unknown	Unk		Not Reported

	Rocephine		C	Intravenous (not otherwise specified)	Unk				Not Reported
	Rovamycine		C	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18360076	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Mental Status Changes	Remdesivir	Y		S				Not Reported
	Alprazolam 1 Mg Po Tid			C				Not Reported
	Dexamethasone 6 Mg Po Daily			C				Not Reported
	Olanzapine 5 Mg Po Qhs			C				Not Reported
	Trazodone 50 Mg Po Qhs			C				Not Reported
	Percocet 5/325 Mg Po Q4h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18360089	DIRECT	Y	OT			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18360219	DIRECT		OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18360610	DIRECT		HO			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspnoea; Hyperhidrosis; Infusion Related Reaction	Remdesivir	Y	S	Intravenous bolus		Gilead
	Enoxaparin		C			Not Reported
	Amlodipine		C			Not Reported
	Ascorbic Acid		C			Not Reported
	Dexamethasone		C			Not Reported
	Zinc		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18360674	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Asorbic Acid			C				Not Reported
	Enoxaparin			C				Not Reported
	Melatonin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ondansetron Prn			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18360698	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Actemra			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Roche

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18360709	DIRECT	Y	LT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatic Failure	Remdesivir	Y		S	Intravenous (not			Not Reported

							otherwise specified)			
		Heparin			C					Not Reported
		Dexamethasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18360941	DIRECT	Y	RI, OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Haemodialysis; Hepatic Failure	Remdesivir For Injection, 100mg/Vial	Y	Y	S	Intravenous (not otherwise specified)	Other Route:Ivpb		Gilead
	Remdesivir For Injection, 100mg/Vial	Y	Y	S				Gilead
	Epoprostenol			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Solu-Medrol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18361135	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497929			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18361367	EXPEDITED (15-DAY)			US-GILEAD-2020-0497930			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18361859	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497913		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bacteraemia; Cardiac Arrest; Death; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Once		Not Reported
	Daptomycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	10 Mg, Qd		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Fluconazole			C		200 Mg, Qd		Not Reported
	Fluconazole			C	Intravenous (not otherwise specified)	400 Mg, Q2hr		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Insulin Regular Hm			C		Unk		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	0.5 G, Q8h		Not Reported
	Metronidazole			C	Intravenous (not otherwise specified)	500 Mg, Q8h		Not Reported
	Micafungin			C	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Zinc Sulfate			C	Oral	220 Mg, Qd		Not Reported
	Plasma			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18362757	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0498020		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hyperhidrosis	Remdesivir			S	Intravenous bolus	200 Mg (Loading Dose)		Gilead
	Enoxaparin			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18362976	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497879			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18362977	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497893			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18363003	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497922			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18363005	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497932			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	"Two Doses"		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18363006	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497917		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Death; Hyperkalaemia; Renal Tubular Necrosis; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported
	Ceftolozane;Tazobactam			C	Intravenous (not otherwise specified)	3 G, Q8h		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg, Once		Not Reported
	Enoxaparin			C	Subcutaneous	80 Mg, Bid		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	0.5 G, Q8h		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Mg, Q6h		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Mg, Bid		Not Reported
	Metronidazole			C	Intravenous (not otherwise specified)	500 Mg, Q8h		Not Reported

Pantoprazole	C	Intravenous (not otherwise specified)	40 Mg, Bid		Not Reported
Piperacillin / Tazobactam	C	Intravenous (not otherwise specified)	3.375 G, Q8h		Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	Unk		Not Reported
Vancomycin	C		500 Mg, Q6h		Not Reported
Zinc Sulfate	C		220 Mg, Qd		Not Reported
Insulin Glargine	C		Unk		Not Reported
Insulin Lispro	C		Unk		Not Reported
Insulin Regular Hm	C		Unk		Not Reported
Plasma	C		Unk		Not Reported
Vasotec [Enalaprilat]	C		Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18363239	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497912			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18363499	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497843			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18363555	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497857			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18363565	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0498037			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	"Two Doses"		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18364248	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Gastrointestinal Haemorrhage; Hospice Care	Remdesivir			S				Gilead
	Albuterol Hf 90 Mcg In Haler 2 Puff 4x/Daily			C				Not Reported
	Calcium Carbonate 1250 Mg Daily			C				Not Reported
	Chlorhexidine Mouthwash 15 Ml Bid			C				Not Reported
	Dexamethasone 10 Mg Iv Q6h			C				Not Reported
	Robitussin Dm 10 Ml Po Q6h			C				Not Reported
	Fentanyl 200 Mcg Iv X1			C				Not Reported
	Midazolam Infusion Titrated			C				Not Reported
	Dulera 100-5 Mcg/Acutation Inhaler 2 Puff Bid			C				Not Reported
	Nystatin 100,000 Unit/Gram Topical Powder Bid			C				Not Reported
	Protonix 40 Mg Iv Q12h			C				Not Reported
	Phenobarb 65 Mg/Ml 100 Mg Nightly Iv			C				Not Reported
	Phenytoin 200 Mg Iv Daily			C				Not Reported
	Miralax 17g Po Daily			C				Not Reported
	Quetiapine 25 Mg Po Bid			C				Not Reported
	Senna 2 Tab Daily Po			C				Not Reported
	Precedex Infusion			C				Not Reported
	Fentayl Infusion			C				Not Reported
	Heparin Infusion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18364525	DIRECT	Y				55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Injection Site Warmth; Swelling Face	Remdesivir For Injection	Y		S		Other Route:Ivpb		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2020	18381849	DIRECT	N				52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Monitoring Procedure Not Performed	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18087678	EXPEDITED (15-DAY)			US-GILEAD-2020-0486660			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy	Remdesivir			S	Transplacental	Unk		Gilead
	Levophed			C	Transplacental	Unk		Not Reported
	Heparin			C	Transplacental	Drip		Not Reported
	Fentanyl			C	Transplacental	Unk		Not Reported
	Lovenox [Levofloxacin]			C	Transplacental	Unk		Not Reported
	Ceftriaxone			C	Transplacental	Unk		Not Reported
	Nimbex [Nimesulide]			C	Transplacental	Unk		Not Reported
	Dexamethasone			C	Transplacental	Unk		Not Reported
	Precedex			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18250000	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0493994		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Death; Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous bolus	200 Mg		Gilead
	Remdesivir			S	Intravenous bolus	100 Mg		Gilead
	Aspirin (E.C.)			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Merrem			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Senna Acutifolia			C		Unk		Not Reported
	Spironolactone			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported
	Plasma			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18300137	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0495926		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cisatracurium Besilate			C		Unk		Not Reported
	Fentanyl Citrate			C		Unk		Not Reported
	Norepinephrine Bitartrate			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Oxygen			C				Not Reported
	Morphine Sulfate			C		Unk		Not Reported

Ondansetron Hcl	C	Unk	Not Reported
Ceftriaxone	C	Unk	Not Reported
Vancomycin Hcl	C	Unk	Not Reported
Albuterol Sulfate	C	Unk	Not Reported
Insulin Lispro	C	Unk	Not Reported
Piperacillin;Tazobactam	C	Unk	Not Reported
Oxycodone Hcl	C	Unk	Not Reported
Donepezil Hcl	C	Unk	Not Reported
Gabapentin	C	Unk	Not Reported
Quetiapine	C	Unk	Not Reported
Ketorolac Tromethamine	C	Unk	Not Reported
Fluoxetine Hcl	C	Unk	Not Reported
Mupirocin	C	Unk	Not Reported
Diphenhydramine	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Alprazolam	C	Unk	Not Reported
Enoxaparin Sodium	C	Unk	Not Reported
Midazolam Hcl	C	Unk	Not Reported
Ketamine Hcl	C	Unk	Not Reported
Polyethylene Glycol [Macrogol]	C	Unk	Not Reported
Albuterol;Ipratropium	C	Unk	Not Reported
Dexmedetomidin	C	Unk	Not Reported
Alteplase Recombinant	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Vasopressin	C	Unk	Not Reported
Phenylephrine	C	Unk	Not Reported
Magnesium Sulfate	C	Unk	Not Reported
Pantoprazole Sodium	C	Unk	Not Reported

	Cefepime	C	Unk	Not Reported
	Plasma-Lyte A	C	Unk	Not Reported
	Sodium Bicarbonate	C	Unk	Not Reported
	Calcium Gluconate	C	Unk	Not Reported
	Meropenem	C	Unk	Not Reported
	Micafungin Sodium	C	Unk	Not Reported
	Fludrocortison	C	Unk	Not Reported
	Heparin Sodium	C	Unk	Not Reported
	Potassium Acetate	C	Unk	Not Reported
	Dextrose In Water	C	Unk	Not Reported
	Potassium Chloride	C	Unk	Not Reported
	Acetaminophen	C	Unk	Not Reported
	Lorazepam	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18362117	EXPEDITED (15-DAY)		OT	ES-ROCHE-2689503		48 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous drip	100mg/24h (Dosis De Carga 200mg)		Not Reported
	Remdesivir			S	Intravenous drip	100mg/24h (Dosis De Carga 200mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18364676	DIRECT	Y				90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapy Interrupted	Remdesivir	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18364679	DIRECT	Y				85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Cholecalciferol			C				Not Reported
	Heparin			C				Not Reported
	Ipratropium			C				Not Reported
	Miralax			C				Not Reported
	Tamsulosin			C				Not Reported
	Timolol Ophthalmic			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18364695	DIRECT	Y	DE			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulseless Electrical Activity; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Zinc Sulfate 220mg Po Daily			C				Not Reported
	Vancomycin Per Protocol			C				Not Reported
	Sulfamethoxazole/Trimethoprim 1600/320mg Iv Q12hr			C				Not Reported
	Melatonin 9mg Po Qhs			C				Not Reported
	Meropenem Renally Dosed			C				Not Reported
	Methylprednisolone 60mg Iv Q6hr			C				Not Reported
	Metronidazole 500mg Iv Q8hr			C				Not Reported
	Micafungin 100mg Iv Daily			C				Not Reported
	Micafungin 100mg Iv Daily			C				Not Reported
	Fluconazole 800mg Iv Once,			C				Not Reported

		Then 400mg Iv Daily X2days, Then X5days								
		Hydroxychloroquine 400mg Po Q12hr			C					Not Reported
		Famotidine 20mg Po Daily			C					Not Reported
		Tobramycin 140mg Iv Once			C					Not Reported
		Ascorbic Acid 1000mg Po Bid			C					Not Reported
		Azithromycin 500mg Iv/Po Daily			C					Not Reported
		Cefepime 1gm Iv Q6hr			C					Not Reported
		Cefepime 2gm Iv Q8hr			C					Not Reported
		Ceftazidime/Avibactam 2.5gm Iv Q8hr			C					Not Reported
		Ceftriaxone 1gm Iv Daily			C					Not Reported
		Convalescent Plasma			C					Not Reported
		Dexamethasone 6mg Iv Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18364863	DIRECT		OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18364986	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urea Increased; Bradycardia; Hypotension; Oxygen Consumption Increased	Remdesivir			S				Not Reported
	Azithromycin Po			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Levothroxine			C				Not Reported
	Pantoprazole			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18365123	DIRECT	Y				62 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Blood Sodium Decreased; Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18365244	DIRECT	Y				11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus	Remdesivir Lyophilized Powder	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18365347	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500mg Tablet			C				Not Reported
	Ceftriaxone 1gm Iv Q24h			C				Not Reported
	Dexamethasone 4mg Iv Q6h			C				Not Reported
	Doxycycline 100mg Iv Once			C				Not Reported
	Enoxaparin 40mg Subq Q12h			C				Not Reported
	Famotidine 20mg Po Bid			C				Not Reported
	Finasteride 5mg Tablet Po Qday			C				Not Reported
	Hctz 12.5mg Po Qday			C				Not Reported
	Losartan 50mg Po Daily			C				Not Reported
	Tamsulosin 0.4mg Po Qday			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18365441	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip	Other Frequency:200 Mg X1, Then Qd;		Gilead
	Tocilizumab (Actemra)			S	Intravenous drip	Other Frequency:Once;		Not Reported
	Albuterol Neb. Soln			C				Not Reported
	Ascorbic Acid Injection			C				Not Reported
	Azithromycin Injection			C				Not Reported
	Benzonatate (Prn)			C				Not Reported
	Budesonide (Pulmicort Respule) Inhalation			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone Na Phos			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin Extended-Release Tablets			C				Not Reported
	Levothyroxine			C				Not Reported
	Multivitamin W/Minerals			C				Not Reported
	Oxycodone			C				Not Reported
	Pantoprazole (Oral)			C				Not Reported
	Rosuvastatin			C				Not Reported
	Zinc Sulfate (Oral)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18365850	DIRECT	Y	HO			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Concentrated Solution			S	Intravenous (not otherwise specified)			Gilead
	Normal Saline 0.9%			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18365860	DIRECT	Y	HO			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir		S	Intravenous (not otherwise specified)		Gilead
	Dexamethasone		C			Not Reported
	Enoxaparin		C			Not Reported
	Guaifenesin		C			Not Reported
	Lidocaine Patch		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18365872	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18366050	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Carvedilol			C				Not Reported
	Torsemide			C				Not Reported
	Dexamethasone			C				Not Reported
	Insulin Regular			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Eplerenone			C				Not Reported
	Epoprostenol			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Hydralazine			C				Not Reported
	Lisinopril			C				Not Reported
	Metolazone			C				Not Reported
	Midazolam			C				Not Reported

	Norepinephrine			C						Not Reported
	Omeprazole			C						Not Reported
	Pantoprazole			C						Not Reported
	Piperacillin-Tazobactam			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18366241	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0498052			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18367089	EXPEDITED (15-DAY)			US-GILEAD-2020-0498044		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18367153	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0498028		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Covid-19 Pneumonia; Death; Hyponatraemia; Hypoxia; Metabolic Acidosis; Respiratory Acidosis	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	10 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	70 Mg, Bid		Not Reported
	Famotidine			C				Not Reported
	Hydroxychloroquine			C				Not Reported

	Insulin Glargine	C		Unk	Not Reported
	Melatonin	C	Oral	6 Mg, Qhs	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	60 Mg, Q6h	Not Reported
	Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	3.375 G, Q6h	Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	1750 Mg, Once	Not Reported
	Zinc Sulphate	C		220 Mg	Not Reported
	Plasma	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18367459	EXPEDITED (15-DAY)			US-GILEAD-2020-0498070			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18367818	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497899			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18367886	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497903		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Cardiac Disorder;	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

Death; Hyperkalaemia	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg, Once	Not Reported
	Azithromycin	C	Oral	500 Mg, Once	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	1 G, Q8h	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	1 G, Q6h	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G, Once	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	10 Mg, Qd	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	10 Mg, Qd	Not Reported
	Enoxaparin	C	Subcutaneous	60 Mg, Bid	Not Reported
	Famotidine	C	Intravenous (not otherwise specified)	20 Mg, Bid	Not Reported
	Famotidine	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, Bid	Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, Qd	Not Reported
	Melatonin	C	Oral	9 Mg	Not Reported
	Meropenem	C	Intravenous (not otherwise specified)	1 G, Q8h	Not Reported
	Prednisone	C	Oral	20 Mg, Once	Not Reported
	Vancomycin	C		Unk	Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	2000 Mg, Once	Not Reported
	Zinc Sulphate	C	Oral	220 Mg, Once	Not Reported
	Insulin Glargine	C		Unk	Not Reported
	Insulin Lispro	C		Unk	Not Reported
	Insulin Regular Hm	C		Unk	Not Reported
	Plasma	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18367972	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0497905		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Zinc Sulfate			C				Not Reported
	Vancomycin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Meropenem			C				Not Reported
	Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18368138	EXPEDITED (15-DAY)			US-GILEAD-2020-0498046		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18368361	EXPEDITED (15-DAY)			US-GILEAD-2020-0498045		33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18375318	DIRECT	Y	OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Fibrin D Dimer Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2020	18375326	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dyspnoea; Pyrexia; Therapy Cessation	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Benzonatate			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Duo-Neb			C				Not Reported
	Methylprednisolone			C				Not Reported
	Montelukast			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sodium Chloride			C				Not Reported
	Verapamil			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2020	18375334	DIRECT	Y				87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Palliative Care; Therapy Cessation	Remdesivir		S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2020	18375345	DIRECT	Y	OT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:200 Mg Once;		Not Reported
	Azithromycin 500 Mg Tab			C				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported
	Dexamethasone 6 Mg Oral Tab			C				Not Reported
	Dexamethasone 6 Mg Iv			C				Not Reported
	Dexamethasone 10 Mg Iv			C				Not Reported
	Famotidine 20 Mg Oral Tab			C				Not Reported
	Hydralazine 20 Mg Iv			C				Not Reported
	Metoprolol 100 Mg Oral Tab			C				Not Reported
	Lisinopril 5 Mg Oral Tab			C				Not Reported
	Propafenone 150 Mg Oral Tab			C				Not Reported
	Xarelto 20 Mg Tab			C				Not Reported
	Multivitamin With Minerals Tab			C				Not Reported
	Zolpidem 10 Mg			C				Not Reported
	Furosemide 20 Mg Iv			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2020	18375361	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Ventricular Extrasystoles; Ventricular Tachycardia	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Aspirin 81mg (Home Med)			C				Not Reported
	Atorvastatin 20mg (Home Med)			C				Not Reported
	Benzonate 200mg Tid			C				Not Reported
	Budesonide/Formoterol (Home Med)			C				Not Reported
	Cilostazol 100mg Bid (Home Med)			C				Not Reported

		Enoxaparin 40mg Sc Daily			C					Not Reported
		Tiotropium 18cmg Inh Daily (Home Med)			C					Not Reported
		Albuterol Inh 2 Puffs Q4h Prn Wheeze (Home Med)			C					Not Reported
		Melatonin 10mg Po Qpm			C					Not Reported
		Zinc Sulfate 100mg Po Bid			C					Not Reported
		Ascorbic Acid 500mg Bid			C					Not Reported
		Furosemide 40mg Po Pid (Home Med)			C					Not Reported
		Cholecalcifierol 25mcg Daily (Home Med)			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2020	18375368	DIRECT	Y	OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury	Remdesivir			S			5 DAY	Not Reported
	Dexamethasone 6 Mg Daily			C				Not Reported
	Ivermectin 18 Mg X1			C				Not Reported
	Monteleukast Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2020	18375377	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2020	18375408	DIRECT	Y	OT			21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous (not			Gilead

Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatine Phosphokinase Increased; Hepatotoxicity; International Normalised Ratio Increased; Prothrombin Time Prolonged; Seizure					otherwise specified)				
	Levetiracetam 1000mg Twice Daily			C					Not Reported
	Dexamethasone 4mg Three Times Daily Orally			C					Not Reported
	Enoxaparin 40mg Subq Daily			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2020	18375449	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Dyspnoea; Respiratory Distress	Remdesivir Iv			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2020	18375613	DIRECT	Y				36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18309887	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0496198		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactate Dehydrogenase Increased; Haemolytic Anaemia; Haptoglobin	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous bolus	200 Unk		Gilead

Decreased; Intentional Product Use Issue; Reticulocyte Count Increased	Remdesivir	S	Intravenous bolus	100 Mg, Qd	Gilead
	Actemra	C		Unk	Not Reported
	Dexamethasone Sodium Phosphate	C		Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C			Not Reported
	Vitamin D [Vitamin D Nos]	C			Not Reported
	Oxygen	C			Not Reported
	Prednisolone	C	Oral		Not Reported
	Aspirin [Acetylsalicylic Acid]	C		81 Mg	Not Reported
	Budesonide	C	Respiratory (inhalation)	Unk	Not Reported
	Ceftriaxone	C		1 G	Not Reported
	Cholecalciferol	C	Oral	5000 Int Units	Not Reported
	Doxycycline	C	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Famotidine	C		20 Mg	Not Reported
	Furosemide	C		40 Mg, Qd	Not Reported
	Guaifenesin	C		600 Mg	Not Reported
	Hydralazine	C		10 Mg, Prn	Not Reported
	Hydrocodone	C		Prn	Not Reported
	Insulin Glargine	C		Unk	Not Reported
	Insulin Lispro	C		Sliding Scale	Not Reported
	Duoneb	C		Unk	Not Reported
	Melatonin	C		Unk	Not Reported
	Methocarbamol	C		Unk	Not Reported
	Quetiapine [Quetiapine Fumarate]	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18369607	EXPEDITED (15-DAY)		OT	ES-ROCHE-2688015			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Heart Injury; Intentional Product Use Issue; Off Label Use	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Lopinavir/Ritonavir	S	Unknown		Not Reported
	Interferon Beta-1b	S	Unknown		Not Reported
	Remdesivir	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18371285	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497926			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18371309	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0497931			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18371414	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0498056			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18372813	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0498043			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Negative; Drug Ineffective	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18374834	EXPEDITED (15-DAY)			US-GILEAD-2020-0498604			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18374882	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0498351		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Unknown	100 Mg		Gilead
	Albuterol [Salbutamol]			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Robitussin Dm			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Dulera			C				Not Reported
	Nystatin			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Phenobarb [Phenobarbital]			C				Not Reported
	Phenytoin			C				Not Reported
	Miralax			C				Not Reported
	Quetiapine			C				Not Reported
	Senna [Sennoside A+B]			C				Not Reported
	Precedex			C				Not Reported
	Heparin			C				Not Reported
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375388	DIRECT	Y	HO			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Cardio-Respiratory Arrest	Remdesivir				S	Intravenous bolus				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375397	DIRECT	Y	HO			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375417	DIRECT	Y				36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375426	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375435	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375443	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Atyr 1923/Placebo Trial			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375456	DIRECT	Y	OT			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Myocardial Infarction; Blood Creatinine Increased	Remdesivir			S				Not Reported
	Clopidogrel 600 Mg			C				Not Reported
	Duo-Neb 0.35-2.5mg/3ml			C				Not Reported
	Midazolam 1mg Injection			C				Not Reported
	Midazolam 2 Mg Injection			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 80 Mg			C				Not Reported
	Enoxaparin 40 Mg Sq			C				Not Reported
	Famotidine 20 Mg			C				Not Reported
	Dilaudid 0.5-1 Mg Prn			C				Not Reported
	Dilaudid Infusion			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Norepinephrine Continuous Iv			C				Not Reported
	Valproic Acid 250 Mg Q8h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375461	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Prns Used: Acetaminophen, Diphenhydramine, Guaifenesin/Dextromet	C		Not Reported
	Ascorbic Acid Injection	C		Not Reported
	Azithromycin Injection	C		Not Reported
	Amiodarone Injection	C		Not Reported
	Calcium Carbonate	C		Not Reported
	Ceftriaxone	C		Not Reported
	Cholecalciferol	C		Not Reported
	Dexamethasone Na Phos	C		Not Reported
	Cisatracurium Drip	C		Not Reported
	Epoprostenol	C		Not Reported
	Escitalopram	C		Not Reported
	Fentanyl Drip	C		Not Reported
	Guaifenesin	C		Not Reported
	Heparin Drip	C		Not Reported
	Sliding Scale Regular Insulin	C		Not Reported
	Ipratropium/Albuterol Inh	C		Not Reported
	Lisinopril/Hydrochlor	C		Not Reported
	Magnesium Sulfate	C		Not Reported
	Norepinephrine Drip	C		Not Reported
	Pantoprazole (Started 10/5) , And Also Zosyn (Started 10/9)	C		Not Reported
	Oxycodone, Potassium Chloride, Propofol, Trazodone, Vasopressin, Zinc	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375469	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dyspnoea; Hypoxia; Pulmonary Oedema; Pulse Absent	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Duloxetine			C				Not Reported
	Metoprolol			C				Not Reported
	Diltiazem			C				Not Reported
	Dexamethasone			C				Not Reported

	Furosemide			C						Not Reported
	Aspirin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375474	DIRECT	Y	HO			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Remdesivir	Y		S		Other Frequency:Total;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375476	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Administration Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375483	DIRECT	Y				70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Insulin Lispro (Humalog) 10 Units			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375497	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hypotension	Remdesivir Eua			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375504	DIRECT		DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375509	DIRECT		DE			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Aortic Valve Incompetence; Bradycardia; Cardiac Failure Congestive; Covid-19 Pneumonia; Hypotension; Left Ventricular Hypertrophy; Mitral Valve Incompetence; Pulmonary Oedema; Respiratory Failure; Tricuspid Valve Incompetence	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375538	DIRECT		DE			89 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Communication Disorder; Confusional State; Delirium; Lung Infiltration; Respiratory Failure	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375543	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Encephalopathy; Haemolysis; Hyperglycaemia; Mental Status Changes; Pneumothorax; Pyrexia; Subcutaneous Emphysema; Thrombocytopenia; Ventricular Fibrillation; Ventricular Tachycardia	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18375548	DIRECT		DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Aspergillus Test Positive; General Physical Health Deterioration; Refusal Of Treatment By Relative	Remdesivir			S				Not Reported
	N/A			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2020	18376378	DIRECT	Y	OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Ear Discomfort; Hypoacusis; Penile Haemorrhage; Tinnitus	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	17805179	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0467261		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	17841427	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468705		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			S	Unknown			Not Reported
	Insulin Aspart			C				Not Reported
	Metoprolol			C				Not Reported
	Cisatracurium			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Vasopressin			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Tocilizumab			C				Not Reported
	Digoxin			C				Not Reported
	Melatonin			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Furosemide			C				Not Reported
	Metolazone			C				Not Reported
	Insulin Glargine			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	17857269	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0468988		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	17951103	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0475616		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Bisacodyl			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported
	Guaifenesin			C				Not Reported
	Hydrocodone Bitartrate And Acetaminophen			C				Not Reported
	Morphine			C				Not Reported
	Orphenadrine			C				Not Reported
	Prednisone			C				Not Reported
	Docusate			C				Not Reported
	Sodium Chloride			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18308044	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0496219		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Ivig [Immunoglobulin]			C				Not Reported
	Morphine			C	Intravenous (not otherwise specified)	4 Mg, Q1hr		Not Reported
	Dexmedetomidine			C	Intravenous (not otherwise specified)	0.7 Mcg/Kg/Hr		Not Reported
	Scopolamine [Hyoscine]			C	Transdermal	1.5 Mg		Not Reported
	Prednisone			C	Oral	40 Mg		Not Reported
	Famotidine			C	Oral	20 Mg		Not Reported
	Escitalopram			C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18375303	EXPEDITED (15-DAY)		DS, HO, OT	SE-BAUSCH-BL-2020-028834			Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Carotid Artery Stenosis; Depressed Level Of Consciousness; Facial Paresis; Muscle Spasticity	Dexamethasone			S	Unknown			Bausch And Lomb
	Cefotaxim			S	Unknown			Not Reported
	Veklury			S	Intravenous (not otherwise specified)	200 Mg, Once, 1 Total		Not Reported
	Eliquis			C				Not Reported
	Entresto			C				Not Reported
	Eplerenone			C				Not Reported
	Bisoprolol			C				Not Reported
	Escitalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18376231	EXPEDITED (15-DAY)			US-GILEAD-2020-0498666		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18376557	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07224			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Foetal Exposure During Pregnancy; Hydronephrosis; Low Birth Weight Baby; Metabolic Acidosis; Neonatal Respiratory Distress Syndrome; Premature Baby; Urinary Tract Obstruction	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Azithromycin			S	Transplacental	Unk		Lupin
	Ceftriaxone			S	Transplacental	Unk		Lupin
	Methylprednisolone			S	Transplacental	Unk		Lupin
	Betamethasone			S	Transplacental	Unk		Lupin
	Insulin			S	Transplacental	Unk		Not Reported
	Heparin			S	Transplacental	Unk		Not Reported
	Remdesivir			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377317	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07143		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Ceftriaxone			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	Unk		Lupin
	Betamethasone			S	Unknown	Unk		Lupin
	Remdesivir			S	Unknown	Unk		Not Reported
	Insulin			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377392	DIRECT	Y	OT			44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377397	DIRECT	Y	OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Continuous Haemodiafiltration	Remdesivir			S				Not Reported
	Dexamethasone 6mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377403	DIRECT	Y	OT			88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Erythema; Infusion Site Extravasation; Infusion Site Oedema; Infusion Site Swelling	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Sterile Water For Injection To Reconstitute Remdesivir			C				Not Reported
	Sodium Chloride 0.9% 250 Ml Solution Diluent			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377406	DIRECT	Y	DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377412	DIRECT	Y	OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Respiratory Disorder	Remdesivir			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377417	DIRECT	Y	OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported
	Tocilizumab 400 Mg			C				Not Reported
	Acetaminophen 650 Mg			C				Not Reported
	Lovenox 40 Mg Sq Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377422	DIRECT	Y				82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377427	DIRECT	Y				21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Doxycycline 100mg Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377432	DIRECT	Y	LT			44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir Eua	Y		S	Intravenous (not			Gilead

Increased; Aspartate Aminotransferase Increased; Hypoxia; Ischaemic Hepatitis					otherwise specified)					
	Amiodarone			C						Not Reported
	Dexmedetomidine			C						Not Reported
	Fentanyl			C						Not Reported
	Heparin			C						Not Reported
	Lansoprazole			C						Not Reported
	Norepinephrine			C						Not Reported
	Propofol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377438	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extra Dose Administered	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377453	DIRECT	Y				85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol			C				Not Reported
	Atorvastatin 10mg			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol 2000 Unit			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Enoxaparin 40mg			C				Not Reported
	Lisinopril 20mg			C				Not Reported
	Folic Acid 1 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18377459	DIRECT	Y				85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia	Remdesivir	S	Intravenous (not otherwise specified)		Gilead
	Albuterol	C			Not Reported
	Atorvastatin 10mg	C			Not Reported
	Ceftriaxone	C			Not Reported
	Cholecalciferol 2000 Unit	C			Not Reported
	Dexamethasone 6mg	C			Not Reported
	Enoxaparin 40mg	C			Not Reported
	Lisinopril 20mg	C			Not Reported
	Folic Acid 1 Mg	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18378179	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0498362		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatic Failure; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ceftriaxone			C		Unk		Not Reported
	Solumedrol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ascorbic Acid			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Plasma			C		Unk		Not Reported
	Epoprostenol			C		Continuous Nebulization, 50ng/Kg/Min		Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18380496	EXPEDITED (15-DAY)		OT	US-ROCHE-2690329		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Tocilizumab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Remdesivir	S	Intravenous (not otherwise specified)	Not Reported
	Dexamethasone	C		Not Reported
	Ascorbic Acid	C		Not Reported
	Cholecalciferol	C		Not Reported
	Famotidine	C		Not Reported
	Furosemide	C		Not Reported
	Memantine	C		Not Reported
	Primidone	C		Not Reported
	Xarelto	C		Not Reported
	Topiramate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18380979	DIRECT	Y	HO			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18380985	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir Injection			S	Intravenous bolus			Gilead
	Lovenox			C				Not Reported
	Zosyn			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18380988	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir Injection			S	Intravenous bolus			Gilead
	Metoprolol			C				Not Reported

	Clonazepam			C						Not Reported
	Ceftriaxone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18380990	DIRECT	Y	OT			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Abnormal; Heart Rate Decreased	Remdesivir Injection			S	Intravenous bolus			Gilead
	Enoxaparin			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18380993	DIRECT	Y	OT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir Injection			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18381009	DIRECT	Y	OT			25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir Injection			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18381013	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir Injection			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18381318	DIRECT	Y	DE, HO, OT			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Vancomycin			C				Not Reported
	Zosyn			C				Not Reported
	Vibramycin			C				Not Reported
	Lactated Ringers			C				Not Reported
	Lasix			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2020	18382298	DIRECT	Y				58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Veklury			S				Not Reported
	Remdesivir (Veklury)			C				Not Reported
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported
	Apap Prn (2 Doses)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18030692	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483267		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Oxygen			C				Not Reported
	Insulin Nph [Insulin Isophane Bovine]			C	Subcutaneous	25 Units		Not Reported
	Insulin Nph [Insulin Isophane Bovine]			C	Subcutaneous	20 Units		Not Reported
	Insulin Nph [Insulin Isophane Bovine]			C	Subcutaneous	Unk		Not Reported

Potassium Chloride	C	Oral	40 Meq, Once	Not Reported
Potassium Chloride	C	Oral	40 Meq, Q4hr	Not Reported
Insulin Regular Hm	C	Subcutaneous	Unk	Not Reported
Insulin Regular Hm	C	Subcutaneous	Unk	Not Reported
Apixaban	C	Other	5 Mg, Bid	Not Reported
Insulin Lispro	C	Subcutaneous	Unk	Not Reported
Insulin Human	C	Subcutaneous	Unk	Not Reported
Insulin Human	C		Unk	Not Reported
Insulin Glargine	C			Not Reported
Sodium Chloride	C			Not Reported
Pantoprazole	C	Oral	40 Mg, Qd	Not Reported
Pantoprazole	C	Oral	40 Mg, Bid	Not Reported
Rocephine	C	Intravenous (not otherwise specified)	1 G, Qd	Not Reported
Rocephine	C	Intravenous (not otherwise specified)	1 Unk	Not Reported
Zithromax	C	Intravenous (not otherwise specified)	250 Mg, Qd	Not Reported
Zithromax	C	Oral	500 Unk	Not Reported
Hydralazine	C	Intravenous (not otherwise specified)	Q6h Prn	Not Reported
Norvasc	C	Other	10 Mg, Qd	Not Reported
Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
Glucagen [Glucagon]	C	Intramuscular	1 Mg	Not Reported
Dextrose In Water	C		Unk	Not Reported
Dextrose	C	Oral	Unk	Not Reported
Glyburide	C	Oral	2.5 Mg, Qd	Not Reported
Lovenox [Enoxaparin Sodium]	C	Subcutaneous	120 Mg, Q12h	Not Reported
Lovenox [Enoxaparin Sodium]	C	Subcutaneous	40 Mg, Bid	Not Reported
Mupirocin	C	Nasal	1 Applic Bid	Not Reported

	Albuterol Sulfate	C	Respiratory (inhalation)	Unk Unk, Q4hr, Prn		Not Reported
	Plasma-Lyte A	C		500 Ml		Not Reported
	Tylenol	C	Other	650 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18249080	EXPEDITED (15-DAY)		DE, HO, LT	BR-ROCHE-2661714		66 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Intestinal Ischaemia; Pneumomediastinum; Pneumothorax	Tocilizumab			S	Intravenous (not otherwise specified)	At 17:50		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose Of Remdesivir Prior To Events Onset: 20/Aug/2020 At 14:49		Not Reported
	Hydroxychloroquine			C				Not Reported
	Azithromycin			C				Not Reported
	Rocuronio			C				Not Reported
	Cisatracurio			C				Not Reported
	Unfractionated Heparin			C				Not Reported
	Clexane			C				Not Reported
	Noradrenaline			C				Not Reported
	Dexamethasone			C				Not Reported
	Hydrocortisone			C				Not Reported
	Meropenem			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18277517	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0495162		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Acetaminophen	C		Unk	Not Reported
	Dexamethasone	C		6 Mg, Qd	Not Reported
	Diphenhydramine	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Fluticasone;Vilanterol	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Iopamidol	C		Unk	Not Reported
	Bio K Plus	C		Unk	Not Reported
	Morphine	C		Unk	Not Reported
	Mvi [Vitamins Nos]	C		Unk	Not Reported
	Ondansetron	C		Unk	Not Reported
	Oxycodone	C		Unk	Not Reported
	Piperacillin / Tazobactam	C		Unk	Not Reported
	Valacyclovir [Valaciclovir]	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18324109	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0496361		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Covid-19; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Plasma			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Keflex [Cefalexin Monohydrate]			C				Not Reported
	Allopurinol			C	Oral	300 Mg		Not Reported
	Heparin			C	Subcutaneous	5000 Units		Not Reported
	Pantoprazole			C	Oral	40 Mg		Not Reported
	Tamsulosin			C	Oral	0.4 Mg		Not Reported

Probenecid And Colchicine	C	Oral	500-0.5mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18381604	EXPEDITED (15-DAY)		LT, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-046			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulation Test Abnormal; Foetal Exposure During Pregnancy; Neonatal Respiratory Depression	Heparin			S	Unknown	Unknown		Westward
	Methylprednisolone			S	Unknown	Unknown		Hikma
	Ceftriaxone			S	Unknown	Unknown		Hikma
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Azithromycin			S	Unknown	Unknwon		Not Reported
	Betamethasone			S	Unknown	Unknown		Not Reported
	Remdesivir			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18382349	DIRECT	Y	LT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18382350	DIRECT	Y				67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Dehydration; Shock	Remdesivir	Y		S	Intravenous bolus			Gilead
	Desmopressin			C				Not Reported
	Dexamethasone			C				Not Reported
	Piperacillin Tazobactam			C				Not Reported
	Propofol			C				Not Reported
	Diltiazem			C				Not Reported

	Aspirin			C						Not Reported
	Doxycycline			C						Not Reported
	Hydrocotrisone			C						Not Reported
	Lorazepam			C						Not Reported
	Enoxaparin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18382356	DIRECT	Y	HO			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Renal Clearance Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18382389	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2020-028950		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Dexamethasone			S	Intramuscular	6 Mg, Qd		Bausch And Lomb
	Remdesivir			S	Intravenous (not otherwise specified)	200mg On D1 Then 100mg D2 To D5		Not Reported
	Ivermectin			S	Oral	18 Mg, Qd		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	100 Ml, Qd		Not Reported
	Enoxaparin			S	Subcutaneous	1000 Iu, Bid		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 G, Tid		Not Reported
	Diffu K			C				Not Reported
	Bisoprolol			C				Not Reported
	Rocephine			C	Intravenous (not otherwise specified)			Not Reported
	Oxygen			C				Not Reported

	Rovamycine (Spiramycin)			C	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18382717	DIRECT	Y	OT			97 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18382848	DIRECT	Y				51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18382870	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Dexamethasone			C				Not Reported
	Methylprednisolone			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18382875	DIRECT		OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18383071	DIRECT	Y	OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Guaifenesin			C				Not Reported
	Insulun			C				Not Reported
	Benzonatate			C				Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18383081	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen 650 Mg			C				Not Reported
	Albuterol Sulfate			C				Not Reported
	Benzonatate 100 Mg			C				Not Reported
	Dexamethasone Injection 6 Mg			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Insulin			C				Not Reported
	Melatonin			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18383669	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0498842		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone	C				Not Reported
	Enoxaparin	C				Not Reported
	Guaifenesin	C				Not Reported
	Lidocaine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18383745	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0498801		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol Hfa			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Benzonatate			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C		Unk		Not Reported
	Duoneb			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Ondasetron [Ondansetron]			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Sodium Chloride			C		Unk		Not Reported
	Verapamil			C		Unk		Not Reported
	Zinc Sulphate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18384123	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0498841		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Amiodarone			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Cisatracurium			C				Not Reported
	Epoprostenol			C				Not Reported
	Escitalopram			C				Not Reported
	Fentanyl			C				Not Reported
	Guaifenesin			C				Not Reported
	Heparin			C				Not Reported
	Regular Insulin Novo Nordisk			C				Not Reported
	Ipratropium/Albuterol			C				Not Reported
	Lisinopril + Hidroclorotiazida			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18384124	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0498798		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18384456	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0498786		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Actemra			S	Intravenous drip	730 Mg, Once		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Benzonatate			C		Unk		Not Reported
	Pulmicort			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Guaifenesin			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Multivitamin And Mineral			C		Unk		Not Reported
	Oxycodone			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18384528	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0498767		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S				Gilead
	Zinc Sulfate			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported

Sulfamethoxazole And Trimethoprim	C	Unk	Not Reported
Melatoniin	C	Unk	Not Reported
Meropenem	C	Renal Dose	Not Reported
Methylprednisolone	C	Unk	Not Reported
Metronidazole	C	Unk	Not Reported
Micafungin	C	Unk	Not Reported
Micafungin	C	Unk	Not Reported
Fluconazole	C	Unk	Not Reported
Hydroxychloroquine	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Tobramycin	C	Unk	Not Reported
Ascorbic Acid	C	Unk	Not Reported
Azithromycin	C	Unk	Not Reported
Cefepime	C	Unk	Not Reported
Cefepime	C	Unk	Not Reported
Avibactam;Ceftazidime	C	Unk	Not Reported
Ceftriaxone	C	Unk	Not Reported
Plasma	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18385961	DIRECT	Y	OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Infusion Site Oedema; Infusion Site Swelling	Remdesivir			S	Intravenous drip			Gilead
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18386415	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir Solution 100 Mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Solution 100 Mg Vial	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q24 Hr ;		Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Amino Acid			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Diltiazem			C				Not Reported
	Duloxetine			C				Not Reported
	Furosemide			C				Not Reported
	Insulin, Regular			C				Not Reported
	Lipid (Smoflipid)			C				Not Reported
	Melatonin			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Mupirocin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Pravastatin			C				Not Reported
	Pregabalin			C				Not Reported
	Telmisartan			C				Not Reported
	Trazodone			C				Not Reported
	Total Parenteral Nutrition			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18386512	DIRECT	Y	DE			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Respiratory Failure; Septic Shock	Remdesivir Solution 100mg Vial	Y	S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Solution 100mg Vial	Y	S	Intravenous (not otherwise specified)	Other Frequency:Q 24 Hr;		Gilead
	Acetaminophen		C				Not Reported
	Albuterol		C				Not Reported
	Albuterol-Ipratropium		C				Not Reported
	Benzonatate		C				Not Reported
	Chlorhexidine		C				Not Reported
	Dexamethasone		C				Not Reported
	Dexmedetomidine		C				Not Reported
	Guaifenesin-Codeine		C				Not Reported
	Insulin Regular		C				Not Reported
	Lidocaine		C				Not Reported
	Melatonin		C				Not Reported
	Morphine Sulfate		C				Not Reported
	Muprocin		C				Not Reported
	Propofol		C				Not Reported
	White Petrolatum-Mineral Oil Eye Ointment		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18386518	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Septic Shock	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q 24 Hr ;		Gilead
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Chlorhexidine			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C		Other Strength:40-80mg;		Not Reported
	Hydrocodone-Acetaminophen			C				Not Reported
	Morphine Sulfate			C				Not Reported
	Mupirocin			C				Not Reported

			Nitroglycerin		C				Not Reported
			Ondansetron		C				Not Reported
			Pantoprazole		C				Not Reported
			Piperacillin-Tazobactam		C				Not Reported
			Promethazine		C				Not Reported
			Propofol		C		Other Strength:5-50mcg;		Not Reported
			Quetiapine		C				Not Reported
			Rivaroxaban		C				Not Reported
			Thiamine		C				Not Reported
			Vancomycin		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18386583	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension; Lung Infiltration; Mental Status Changes; Respiratory Failure	Remdesivir Solution 100mg Vial	Y		S		Other Route:Iv		Gilead
	Remdesivir Solution 100mg Vial	Y		S		Other Route:Iv		Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Aztreonam			C				Not Reported
	Calcium Chloride			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Diltiazem			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Aspart			C				Not Reported
	Morphine Sulfate			C				Not Reported
	Ondansetron			C				Not Reported
	Oxycodone			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Propofol			C				Not Reported
	Simethicone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18386597	DIRECT	Y	DE			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypoxia; Respiratory Failure; Unresponsive To Stimuli	Remdesivir Solution 100 Mg Vial	Y	S	Intravenous (not otherwise specified)	Other Route:Iv		Gilead
	Remdesivir Solution 100mg Vial	Y	S	Intravenous (not otherwise specified)	Other Route:Iv		Gilead
	Acetaminophen		C				Not Reported
	Albuterol		C				Not Reported
	Aspirin		C				Not Reported
	Benzonatate		C				Not Reported
	Carvedilol		C				Not Reported
	Chlorhexidine		C				Not Reported
	Dexamethasone		C				Not Reported
	Dextromethorphan-Guaifenesin		C				Not Reported
	Enoxaparin		C				Not Reported
	Gabapentin		C				Not Reported
	Insulin Detemir		C				Not Reported
	Insulin, Regular		C				Not Reported
	Levothyroxine		C				Not Reported
	Lisinopril		C				Not Reported
	Loperamide		C				Not Reported
	Melatonin		C				Not Reported
	Mupirocin		C				Not Reported
	Ondansetron		C				Not Reported
	Pantoprazole		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18386802	DIRECT	Y	DE			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Condition Aggravated	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q 24 Hr;		Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Carvedilol			C				Not Reported
	Ceftaroline			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported

		Enoxaparin			C					Not Reported
		Haloperidol Lactate			C					Not Reported
		Hydromorphone			C					Not Reported
		Insulin Aspart			C					Not Reported
		Ondansetron			C					Not Reported
		Pyridoxine (Vitamin B6)			C					Not Reported
		Vancomycin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18386853	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Delirium; General Physical Health Deterioration; Respiratory Distress; Respiratory Failure	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Other Route:Iv		Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q24hr; Other Route:Iv		Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Atorvastatin			C				Not Reported
	Benzonatate			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Hydrocodone-Chlorpheniramine			C				Not Reported
	Lorazepam			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Ondasetron			C				Not Reported
	Oxymetazoline			C				Not Reported
	Senna - Docusate 8.5 - 50			C				Not Reported
	Verapamil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18386857	DIRECT	Y	DE			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

General Physical Health Deterioration; Pulse Absent	Remdesivir Solution 100 Mg Vial Y	S	Intravenous (not otherwise specified)	Gilead
	Remdesivir Solution 100 Mg Vial Y	S	Intravenous (not otherwise specified)	Gilead
	Acetaminophen	C		Not Reported
	Albuterol	C		Not Reported
	Aspirin	C		Not Reported
	Baclofen	C		Not Reported
	Chlorhexidine	C		Not Reported
	Clonidine	C		Not Reported
	Dexamethasone	C		Not Reported
	Enoxaparin	C		Not Reported
	Famotidine	C		Not Reported
	Furosemide	C		Not Reported
	Gabapentin	C		Not Reported
	Haloperidol Lactate	C		Not Reported
	Insulin Detemir	C		Not Reported
	Insulin Regular	C		Not Reported
	Levetriacetam	C		Not Reported
	Melatonin	C		Not Reported
	Meropenem	C		Not Reported
	Metoprolol Tartrate	C		Not Reported
	Morphine Sulfate Sr	C		Not Reported
	Mupirocin	C		Not Reported
	Norepinephrine	C		Not Reported
	Ondansetron	C		Not Reported
	Phenytoin	C		Not Reported
	Piperacillin-Tazobactam	C		Not Reported
	Polyethylene Glycol	C		Not Reported
	Potassium Chloride	C		Not Reported
	Quietiapine	C		Not Reported
	Simvastatin	C		Not Reported
	Tramadol	C		Not Reported
	Vancomycin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18386887	DIRECT	Y	DE			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest X-Ray Abnormal; Fatigue; Lethargy; Pyrexia; Seizure Like Phenomena; Unresponsive To Stimuli	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)		Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)		Gilead
	Acetmainophen			C			Not Reported
	Albuterol			C			Not Reported
	Baclofen			C			Not Reported
	Bisocodyl			C			Not Reported
	Ceftriaxone			C			Not Reported
	Dexamethasone			C			Not Reported
	Docusate			C			Not Reported
	Enalapril			C			Not Reported
	Enoxaparin			C			Not Reported
	Hydralazine			C			Not Reported
	Hydrocodone-Chlorpheniramine			C			Not Reported
	Lactulose			C			Not Reported
	Lamotrigine			C			Not Reported
	Levetiracetam			C			Not Reported
	Lorazepam			C			Not Reported
	Meropenem			C			Not Reported
	Metoprolol Tartrate			C			Not Reported
	Ondansetron			C			Not Reported
	Oxcarbazepine			C			Not Reported
	Piperacillin-Tazobactam			C			Not Reported
	Polyethylene Glycol			C			Not Reported
	Potassium Chloride			C			Not Reported
	Sertraline			C			Not Reported
	Sodium Phosphate			C			Not Reported
	Valproic Acid Na			C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18387012	DIRECT	Y	DE			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Atrial Fibrillation; Cardiac Arrest; Gastrointestinal Haemorrhage; Hypotension; Renal	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q 24 Hr;		Gilead
	Acetaminophen			C				Not Reported

Impairment; White Blood Cell Count Increased	Apixaban	C	Not Reported
	Ascorbid Acid (Vitamin C)	C	Not Reported
	Atorvastatin	C	Not Reported
	Cefazolin	C	Not Reported
	Chlorhexidine	C	Not Reported
	Cholecalciferol (Vitamin D3)	C	Not Reported
	Dexamethasone	C	Not Reported
	Dexmedetomidine	C	Not Reported
	Diltiazem	C	Not Reported
	Furosemide	C	Not Reported
	Insulin, Regular	C	Not Reported
	Metoprolol	C	Not Reported
	Midazolam	C	Not Reported
	Morphine Sulfate	C	Not Reported
	Mupirocin	C	Not Reported
	Norephinephrine	C	Not Reported
	Ondansetron	C	Not Reported
	Patiromer Calcium Sorbitex	C	Not Reported
	Piperacillin-Tazobactam	C	Not Reported
	Propofol	C	Not Reported
	Sodium Bicarbonate	C	Not Reported
	Sodium Bicarbonate/D5w	C	Not Reported
	Vancomycin	C	Not Reported
	Zinc Sulfate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2020	18387152	DIRECT	Y	DE			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Chest X-Ray Abnormal; Condition Aggravated; Hypoventilation; Respiratory Distress; Shock	Remdesivir Solution 100mg Vial			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Solution 100mg Vial			S		Other Frequency:Q 24 Hr ;		Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C		Other Strength:2 Puffs ;		Not Reported
	Alprazolam			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Ceftriazone			C				Not Reported
	Chlorhexidine			C				Not Reported

	Dexamethasone	C		Not Reported
	Dexmedetomidine	C		Not Reported
	Duloxetine	C		Not Reported
	Enalapril	C		Not Reported
	Enoxaparin	C	Other Strength:60-80mg ;	Not Reported
	Famotidine	C		Not Reported
	Fentanyl	C		Not Reported
	Furosemide	C		Not Reported
	Gabapentin	C		Not Reported
	Guaifenesin	C		Not Reported
	Hydralazine	C		Not Reported
	Hydrocodone Acetaminophen	C		Not Reported
	Insulin Aspart	C		Not Reported
	Ipratropium	C	Other Strength:2 Puffs ;	Not Reported
	Levothyroxine	C		Not Reported
	Melatonin	C		Not Reported
	Mupirocin	C		Not Reported
	Norepinephrine	C		Not Reported
	Ondansetron	C		Not Reported
	Piperacillin-Tazobactam	C		Not Reported
	Propofol	C	Other Strength:5-50ug;	Not Reported
	Tramadol	C		Not Reported
	Tamsulosin	C		Not Reported
	Vanuronium	C	Other Strength:0.5-1.5 mcg/Kg/Min;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18205100	EXPEDITED (15-DAY)		HO	US-ROCHE-2663390		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bacteraemia; Bacteraemia; Sepsis; Urinary Tract Infection	Tocilizumab			S	Intravenous (not otherwise specified)	On The Same Date, Received Most Recent Dose Medication		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Rdv Loading Dose Followed By One Infusion Of Tcz On Day 1, And A Once-Daily Maintenance Dose Of Remd		Not Reported

	Cefepime	C			Not Reported
	Esomeprazole	C			Not Reported
	Ondansetron	C			Not Reported
	Ondansetron	C			Not Reported
	Lopressor	C			Not Reported
	Insulin Regular	C		50 Units	Not Reported
	Lovenox	C			Not Reported
	Atorvastatin	C			Not Reported
	Acetaminophen	C			Not Reported
	Propofol	C		0.418	Not Reported
	Oxygen	C			Not Reported
	Voriconazole	C			Not Reported
	Voriconazole	C			Not Reported
	Sildenafil	C			Not Reported
	Chlorhexidine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18354009	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2020-028192		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchopleural Fistula; Mucormycosis; Product Use In Unapproved Indication	Dexamethasone			S	Unknown	Steroid Course, Immunosuppressive Therapy		Bausch And Lomb
	Dexamethasone			S				Bausch And Lomb
	Tocilizumab			S	Unknown	Immunosuppressive Therapy		Not Reported
	Tocilizumab			S				Not Reported
	Ceftriaxone			S	Unknown	Empiric Antibiotics		Not Reported
	Ceftriaxone			S				Not Reported
	Azithromycin			S	Unknown	Empiric Antibiotics		Not Reported
	Azithromycin			S				Not Reported
	Enoxaparin			S	Unknown	Low-Weight-Molecular Heparin		Not Reported
	Enoxaparin			S				Not Reported
	Remdesivir			S	Unknown	Antiviral Therapy		Not Reported
	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18384952	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-263982		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18385335	EXPEDITED (15-DAY)			US-GILEAD-2020-0498851			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18386024	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-263988		25 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apgar Score Abnormal; Coagulation Test Abnormal; Decreased Activity; Foetal Exposure During Pregnancy; Metabolic Acidosis; Neonatal Respiratory Distress Syndrome; Perinatal Depression;	Azithromycin			S	Transplacental	Unk		Sun
	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Heparin			S	Transplacental	Unk		Not Reported
	Remdesivir			S	Transplacental	Unk		Not Reported

Premature Baby

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18386827	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Norepinephrine			C				Not Reported
	Phenylephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18386831	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Liquid	Y		S	Intravenous (not otherwise specified)	Other Frequency:Event Description;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18386835	DIRECT	Y				39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Aspartate Aminotransferase Increased; Contraindicated Product Administered	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18386841	DIRECT	Y	OT			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Liver Function Test Increased; Renal Impairment; Therapy Cessation	Remdesivir	Y	S	Intravenous bolus	Gilead
	Ceftriaxone		C		Not Reported
	Morphine		C		Not Reported
	Dexamethasone		C		Not Reported
	Insulin Glargine		C		Not Reported
	Abixaban		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18386842	DIRECT	Y				49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead
	Apixaban			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387048	DIRECT	Y				35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Frequency:Am; Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387083	DIRECT	Y				66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Asthenia; Dysarthria	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387088	DIRECT	Y				79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Dexmedetomide Iv 400mcg/100ml Ns			C				Not Reported
	Aziithromycin 500mg/250ml Iv Ns			C				Not Reported
	Phenylephrine 100mg/250ml Ns			C				Not Reported
	Plasma-Lyte Iv 250ml			C				Not Reported
	Sodium Bicarbonate 50meq Inj			C				Not Reported
	Piperacillin/Tacobactam 2.25gm Iv			C				Not Reported
	Methylprednisolone 40mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387092	EXPEDITED (15-DAY)		DE, DS, HO, LT	JP-PFIZER INC-2020393603		68 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome	Solu-Cortef			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Meropenem			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Linezolid			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Veklury			S	Intravenous (not otherwise specified)	200 Mg, Qd		Not Reported
	Veklury			S	Intravenous (not otherwise specified)	200 Mg, Qd		Not Reported
	Noradrenaline Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pitressin [Vasopressin]			S	Intravenous (not	Unk		Not Reported

			otherwise specified)	
	Avigan	C	Unk	Not Reported
	Alvesco	C	Unk	Not Reported
	Vancomycin	C	Unk	Not Reported
	Heparin	C	Unk	Not Reported
	Dalacin C [Clindamycin Hydrochloride]	C	Unk	Not Reported
	Neuart	C	Unk	Not Reported
	Venilon	C	Unk	Not Reported
	Alinamin [Prosultiamine]	C	Unk	Not Reported
	Vitacimin	C	Unk	Not Reported
	Omeprazole	C	Unk	Not Reported
	Midazolam	C	Unk	Not Reported
	Dexmedetomidine Hydrochloride	C	Unk	Not Reported
	Fentanyl	C	Unk	Not Reported
	Onoact	C	Unk	Not Reported
	Amiodarone Hydrochloride	C	Unk	Not Reported
	Unasyna [Sultamicillin Tosilate]	C	Unk	Not Reported
	Precedex	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387093	DIRECT	Y				44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Ascorbic Acid 500 Mg Po			C				Not Reported
	Vitamin D 5000 Units			C				Not Reported
	Dexamethasone Iv			C				Not Reported
	Famotidine 20 Mg Po			C				Not Reported
	Magensium 2 Gm Iv			C				Not Reported
	Zinc 220 Mg Po			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387157	DIRECT	Y				51 YR	Intersex	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytosis	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387158	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Levothyroxine 100mcg Daily			C				Not Reported
	Vitamin C 500mg Daily			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported
	Enoxaparin 90mg Sq Q12h			C				Not Reported
	Acetaminophen 650mg Q6h Prn			C				Not Reported
	Famotidine 20mg Daily			C				Not Reported
	Cholecalciferol 25mcg			C				Not Reported
	Senna/Docusate 8.6/50mg Daily			C				Not Reported
	Monteleukast 10mg Daily			C				Not Reported
	Amlodipine 10mg Daily			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Prednisone 40mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387165	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)			Gilead
	Exthara Seraph Blood Filter			C				Not Reported
	Epinephrine			C				Not Reported
	Bicarb			C				Not Reported

	Calcium			C					Not Reported
	Norapinephrine			C					Not Reported
	Vasoprassin			C					Not Reported
	Cefepime			C					Not Reported
	Dexamethasone			C					Not Reported
	Pantoprazole			C					Not Reported
	Patrolatum			C					Not Reported
	Heparin			C					Not Reported
	Enoxaparin			C					Not Reported
	Cvvh Hemodialysis			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387169	DIRECT					78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387287	DIRECT	Y				76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Therapy Cessation	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported
	Carvedilol (Carvedilol 12.5mg Tab)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387307	DIRECT	Y	HO			69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387336	DIRECT	Y	CA			28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387348	DIRECT	Y	DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387364	DIRECT	Y	RI			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387380	DIRECT	Y				61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387381	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aspartate	Remdesivir		S	Intravenous bolus	Other Frequency:Once;		Gilead
Aminotransferase Increased	Remdesivir		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387404	DIRECT	Y				72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytosis	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387425	DIRECT	Y	DE			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Seizure	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387463	DIRECT	Y	HO			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir 5 Mg/Ml Solution			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387504	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Erythema;	Remdesivir			S				Not Reported

Infusion Site Extravasation; Infusion Site Extravasation; Infusion Site Swelling

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387530	DIRECT	Y				81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palliative Care	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387562	DIRECT	Y				88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palliative Care	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18387576	DIRECT	Y				47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18390150	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0499054		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Chest Pain; Death; Pulseless Electrical Activity; Troponin Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			C		Unk		Not Reported

Zosyn	C	Unk	Not Reported
Vibramycine	C	Unk	Not Reported
Lactated Ringers	C	Unk	Not Reported
Lasix [Furosemide]	C	Unk	Not Reported
Azithromycin	C	Unk	Not Reported
Ceftriaxone	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Plasma	C	Unk	Not Reported
Heparin	C		Not Reported
Doxycycline	C		Not Reported
Epinephrine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18391187	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Veklury	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18391194	DIRECT					77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18391402	DIRECT	Y				50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

	Remdesivir (Eua) (Remdesivir (Eua))			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18391738	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)			Gilead
	Exthera Seraph Blood Filter			C				Not Reported
	Epinephrine			C				Not Reported
	Bicarb			C				Not Reported
	Calcium			C				Not Reported
	Epinephrine (2mcg/Mln Iv)			C				Not Reported
	Norapinephrine			C				Not Reported
	Vasopressin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Pantoprazole			C				Not Reported
	Petrolatum			C				Not Reported
	Heparine			C				Not Reported
	Enoxaparin			C				Not Reported
	Cvvh Hemodialysis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18392040	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; General Physical Health Deterioration; Hyperthermia; Hypotension; Respiratory Failure	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18392067	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2020	18392097	DIRECT	Y				71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18391790	DIRECT	Y	DE			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392018	DIRECT	Y				38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Feeling Abnormal; Nausea; Palpitations	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Loperamide 2mg Po Q6h			C				Not Reported
	Ondansetron 4mg Iv Q6h Prn			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Enoxaparin 40mg Sq Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392073	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Pulmonary Oedema; Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Dialysis; Electrolyte Imbalance; Intestinal Ischaemia; Liver Function Test Abnormal; Metabolic Acidosis; Oxygen Saturation Decreased; Pneumonia Pseudomonal; Pneumonia Staphylococcal; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY	Gilead
	Allopurinol 100mg Daily			C				Not Reported
	Aspirin 325mg Daily			C				Not Reported
	Azithromax			C				Not Reported
	Atorvastatin 20mg			C				Not Reported
	Vitamin D3 125mcg			C				Not Reported
	Dexamethason 6mg Iv Daily			C				Not Reported
	Dexamethason 4mg Q6			C				Not Reported
	Lovenox 100mg Every 12 Hours			C				Not Reported
	Gabapentin 600mg Twice Daily			C				Not Reported
	Heparin Drip			C				Not Reported
	Insulin Therapy			C				Not Reported
	Merrem 1g Iv Q8			C				Not Reported
	Protonix 40mg Iv Daily			C				Not Reported
	Vancomycin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Nimbex			C				Not Reported
	Precedex			C				Not Reported
	Sodium Bicarb Ggt			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Levophed Ggt			C				Not Reported
	Phenylephrine Ggt			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392121	DIRECT	Y				40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Chills; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Benzonatate			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Influenza Vaccine			C				Not Reported
	Melatonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392291	DIRECT	Y	LT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Lung Assist Device Therapy	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392396	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Dyspnoea; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392401	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Carboxymethylcellulose			C				Not Reported
	Chlorhexidine Gluconate			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lorazepam			C				Not Reported
	Melatonin			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Dexamethasone			C				Not Reported
	Norepinephrine			C				Not Reported
	Sennosides Docusate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392410	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Product Dosage Form Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Enoxaparin 40mg Qd Daily			C				Not Reported
	Ceftriaxone 1gm Q24h			C				Not Reported
	Methylprednisolone 60mg Q12h			C				Not Reported
	Dextromethorphan/Guaifenacin 30/600mg Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392559	DIRECT	Y	OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Product Formulation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Methylprednisolone 40mg Q8h			C				Not Reported
	Fioricel 50/325/40mg			C				Not Reported
	Gabapentin 100mg Q8h Prn			C				Not Reported
	Aspirin 81mg Daily			C				Not Reported
	Ceftriaxone 1gm Iv Q24h			C				Not Reported
	Lacobacillus/Strepcoccus (Risaquad) Probiotic Daily			C				Not Reported
	Benzonatate 100mg Tid Prn			C				Not Reported
	Enoxaparin 40mg Sq Daily			C				Not Reported
	Famotidine 20mg Q12h			C				Not Reported
	Monteleukast 10mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392634	DIRECT	Y				31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir	Y		S	Intravenous (not			Gilead

Increased						otherwise specified)				
	Dexamethasone			C						Not Reported
	Rivaroxaban			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392639	DIRECT	Y	HO			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Dizziness; Dyspnoea; Nausea; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip		5 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392647	DIRECT	Y	HO			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Total Received;		Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392933	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0499386		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Respiratory Failure; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Albuterol [Salbutamol]			C	Respiratory	2 Dosage Form		Not Reported

			(inhalation)		
	Albuterol;Ipratropium	C	Respiratory (inhalation)	3 Ml	Not Reported
	Benzonatate	C	Oral	100 Mg, Tid	Not Reported
	Chlorhexidine	C	Oral	15 Ml, Bid	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Bid	Not Reported
	Dexmedetomidine	C	Intravenous (not otherwise specified)		Not Reported
	Guaifenesin & Codeine	C	Oral	5 Ml	Not Reported
	Insulin Regular Hm	C	Subcutaneous	Unk	Not Reported
	Lidocaine	C	Respiratory (inhalation)	2 Ml, Q3hr	Not Reported
	Melatonin	C	Oral	6 Mg, Qd	Not Reported
	Morphine Sulfate	C	Intravenous (not otherwise specified)	2 Mg, Q4hr	Not Reported
	Mupirocin	C	Nasal	Unk, Bid	Not Reported
	Propofol	C	Intravenous (not otherwise specified)	5-50 Mcg/Kg/Min	Not Reported
	White Petrolatum	C	Ophthalmic	Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18392959	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0499377		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg, Q6h Prn		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Oral	81 Mg, Qd		Not Reported
	Chlorhexidine			C		15 Ml, Bid		Not Reported

Clopidogrel	C	Other	75 Mg, Qd	Not Reported
Dexmedetomidine	C	Intravenous (not otherwise specified)	16 Mcg/Hr	Not Reported
Enoxaparin	C	Subcutaneous	40-80 Mg, Q 12-24 Hr	Not Reported
Hydrocodone/Acetaminophen	C	Oral	1 Dosage Form, Q4hr, Prn	Not Reported
Morphine Sulfate	C	Intravenous (not otherwise specified)	2 Mg, Q1hr	Not Reported
Mupirocin	C	Nasal	Unk Unk, Bid	Not Reported
Nitroglycerin	C		0.4 Mg Q 5 Min Prn	Not Reported
Ondansetron	C	Intravenous (not otherwise specified)	4 Mg, Q6h, Prn	Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported
Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	4.5 Mg	Not Reported
Promethazine	C		6.25 Mg, Q6h Prn	Not Reported
Propofol	C	Intravenous (not otherwise specified)	5-50 Mcg/Kg/Min	Not Reported
Quetiapine	C	Oral	25 Mg, Qhs	Not Reported
Rivaroxaban	C	Oral	15 Mg, Bid	Not Reported
Thiamine	C	Oral	100 Mg, Qd	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	1500 Mg, Q12h	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18393274	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0499400		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Death; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

	Acetaminophen	C	Oral	650 Mg, Prn	Not Reported
	Albuterol [Salbutamol]	C	Respiratory (inhalation)	2 Dosage Form, Prn	Not Reported
	Aspirin 81	C	Oral	81 Mg, Qd	Not Reported
	Carvedilol	C	Oral	6.25 Mg, Bid	Not Reported
	Ceftaroline	C	Intravenous (not otherwise specified)	400 Mg, Bid	Not Reported
	Clopidogrel	C	Oral	75 Mg, Qd	Not Reported
	Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
	Enoxaparin	C	Subcutaneous	40 Mg, Qd	Not Reported
	Haloperidol Lactate	C		2 Mg, Prn	Not Reported
	Hydromorphone	C	Intravenous (not otherwise specified)	0.2 Mg, Prn	Not Reported
	Insulin Aspart	C	Subcutaneous	Unk, Prn	Not Reported
	Ondansetron	C	Intravenous (not otherwise specified)	4 Mg, Prn	Not Reported
	Pyridoxine	C	Oral	50 Mg, Qd	Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	1500 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18393294	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0499423		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg, Q4hr		Not Reported
	Albuterol [Salbutamol Sulfate]			C	Respiratory (inhalation)	2 Puffs		Not Reported

Aspirin [Acetylsalicylic Acid]	C	Oral	81 Mg, Qd	Not Reported
Baclofen	C	Oral	5 Mg, Tid	Not Reported
Chlorhexidine	C		15 Ml, Bid	Not Reported
Clonidine	C	Oral	0.1 Mg, Bid	Not Reported
Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
Enoxaparin	C	Subcutaneous	80 Mg, Qd	Not Reported
Famotidine	C	Oral	20 Mg, Qd	Not Reported
Furosemide	C	Oral	40 Mg	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	20-40 Mg Prn	Not Reported
Gabapentin	C		400 Mg, Tid	Not Reported
Haloperidol Lactate	C	Intramuscular	5 Mg, Q2hr	Not Reported
Insulin Detemir	C	Subcutaneous	50 Iu, Bid	Not Reported
Insulin Regular Hm	C	Subcutaneous	0-10 Units Prn	Not Reported
Levetiracetam	C		750 Mg, Bid	Not Reported
Melatonin	C	Oral	6 Mg, Qd	Not Reported
Meropenem	C	Intravenous (not otherwise specified)	500 Mg, Bid	Not Reported
Metoprolol Tartrate	C	Oral	50 Mg, Bid	Not Reported
Morphine Sulfate	C	Intravenous (not otherwise specified)	2 Mg, Q2hr	Not Reported
Mupirocin	C	Nasal	Bid	Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)	0.02 Mcg/Kg/Min	Not Reported
Ondansetron	C	Intravenous (not otherwise specified)	4 Mg, Tid	Not Reported
Phenytoin	C	Oral	200 Mg, Bid	Not Reported
Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	3.375-4.5 Gm	Not Reported
Polyethylene Glycol 3350	C	Oral	17 G, Qd	Not Reported

	Potassium Chloride	C	Oral	20 Meq, Bid		Not Reported
	Quetiapine	C	Oral	200 Mg, Bid		Not Reported
	Quetiapine	C		300 Mg, Bid		Not Reported
	Simvastatin	C	Oral	40 Mg, Qd		Not Reported
	Tramadol	C		100 Mg, Q6h		Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	1500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18393341	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0499383		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once		Gilead
	Acetaminophen			C	Oral	650 Mg, Prn		Not Reported
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	2 Dosage Form, Prn		Not Reported
	Aztreonam			C	Intravenous (not otherwise specified)	1000 Mg, Q8h		Not Reported
	Calcium Chloride			C	Intravenous (not otherwise specified)	1 G, Prn		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Dexmedetomidine			C	Intravenous (not otherwise specified)	0.4 Mcg/Kg/Min		Not Reported
	Diltiazem			C	Intravenous (not otherwise specified)	5 Mg/Hr		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg, Bid		Not Reported
	Insulin Aspart			C	Subcutaneous	Unk Unk, Prn		Not Reported

	Morphine Sulfate		C	Intravenous (not otherwise specified)	4 Mg, Prn		Not Reported
	Ondansetron		C	Intravenous (not otherwise specified)	4 Mg, Prn		Not Reported
	Oxycodone		C	Oral	5 Mg, Prn		Not Reported
	Polyethylene Glycol [Macrogol]		C	Oral	17 G, Bid		Not Reported
	Propofol		C	Intravenous (not otherwise specified)	5 Mcg/Kg/Min		Not Reported
	Simethicone		C	Oral	160 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18393715	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0498983		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Loading Dose (D8)		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Maintenance (D9)		Gilead
	Nitroglycerin			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18394527	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0499412		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Atorvastatin			C				Not Reported
	Benzonatate			C				Not Reported
	Clopidogrel			C				Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Hydrocodone			C				Not Reported
	Chlorpheniramine [Chlorphenamine]			C				Not Reported
	Lorazepam			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Ondansetron			C				Not Reported
	Oxymetazoline			C				Not Reported
	Docusate;Senna			C				Not Reported
	Verapamil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18394941	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0499414		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Apixaban			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Cefazolin			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Diltiazem			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Regular [Insulin Bovine]			C				Not Reported
	Metoprolol			C				Not Reported
	Midazolam			C				Not Reported
	Morphine Sulfate			C				Not Reported
	Mupirocin			C				Not Reported
	Norepinephrine			C				Not Reported

	Ondansetron	C	Not Reported
	Patiromer Sorbitex Calcium	C	Not Reported
	Piperacillin & Tazobactam	C	Not Reported
	Propofol	C	Not Reported
	Sodium Bicarbonate	C	Not Reported
	Vancomycin	C	Not Reported
	Zinc Sulfate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18396905	DIRECT	Y	OT			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18396944	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Feeling Abnormal; Hypoaesthesia Oral; Paraesthesia Oral; Urticaria	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18396948	DIRECT	Y				35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg X1,100mg Qd;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2020	18396952	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2020	18396956	DIRECT	Y	OT			86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Hydrochlorothiazide			C				Not Reported
	Lisinopril			C				Not Reported
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Atorvastatin			C				Not Reported
	Clopidogrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18395830	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0499349		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Albuterol Hfa			C		Unk		Not Reported
	Atorvastatin			C		10 Mg		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Cholecalciferol			C		2000 Unit		Not Reported
	Dexamethasone			C		6 Mg		Not Reported
	Enoxaparin			C		40 Mg		Not Reported
	Lisinopril			C		20 Mg		Not Reported
	Folic Acid			C		1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18395831	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0499374		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; General Physical Health Deterioration; Oxygen Saturation Decreased; Seizure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg, Q8h, Prn		Not Reported
	Albuterol Hfa			C	Respiratory (inhalation)	2 Puffs, Qid And Prn		Not Reported
	Baclofen			C	Oral	20 Mg, Tid		Not Reported
	Bisacodyl			C	Rectal	10 Mg, Tid		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Dexamethasone			C	Oral	6 Mg, Qd		Not Reported
	Docusate			C		100 Mg, Bid		Not Reported
	Enalapril			C	Oral	10 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Chlorpheniramine;Hydrocodone			C	Oral	5 Ml, Q 12 Hr Prn		Not Reported
	Lactulose			C		30 G, Q6h		Not Reported
	Lamotrigine			C		200 Mg, Bid		Not Reported
	Levetiracetam			C		500 Mg, Bid		Not Reported
	Lorazepam			C	Oral	1 Mg, Q4hr, Prn		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported
	Metoprolol Tartrate			C		25 Mg, Qd		Not Reported
	Ondansetron			C	Intravenous (not otherwise specified)	4 Mg, Q8h, Prn		Not Reported
	Oxcarbazepine			C		600 Mg, Bid		Not Reported

	Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	3.375-4.5 Gm		Not Reported
	Polyethylene Glycol 3350	C		17 G, Bid		Not Reported
	Potassium Chloride	C		20 Meq, Qd		Not Reported
	Sertraline	C		75 Mg, Qd		Not Reported
	Sodium Phosphate	C	Rectal	1 Enema Once		Not Reported
	Valproic Acid Sodium	C		500 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18395832	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0499410		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Benzonatate			C				Not Reported
	Carvedilol			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Dextromethorphan-Guaifenesin			C				Not Reported
	Enoxaparin			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Detemir			C				Not Reported
	Insulin Regular [Insulin Bovine]			C				Not Reported
	Levothyroxine			C				Not Reported
	Lisinopril			C				Not Reported
	Loperamide			C				Not Reported
	Melatonin			C				Not Reported
	Mupirocin			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18395916	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0499404		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Clinimix E			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Dexamethasone			C				Not Reported
	Diltiazem			C				Not Reported
	Duloxetine			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Regular [Insulin Bovine]			C				Not Reported
	Smoflipid			C				Not Reported
	Melatonin			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Mupirocin			C				Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Pravastatin			C				Not Reported
	Pregabalin			C				Not Reported
	Telmisartan			C				Not Reported
	Trazodone			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18396922	DIRECT	Y	OT			17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18396926	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Injury	Remdesivir			S			5 DAY	Not Reported
	Dexamethasone			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Vitamin D			C				Not Reported
	Losartan			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18396931	DIRECT	Y	OT			47 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen 650 Mg Q4h Prn			C				Not Reported
	Albuterol 90 Mcg Mdi Q4h Prn			C				Not Reported
	Asapirin 81 Mg Daily			C				Not Reported
	Budesonide 1 Mg Nebulizer At Bedtime			C				Not Reported
	Enoxaparin 60 Mg Twice Daily			C				Not Reported
	Ondansetron 4 Mg Ivp Q4h Prn N/V			C				Not Reported
	Trazodone 50 Mg At Bedtime			C				Not Reported
	Metronidazole 500 Mg Iv Q8h			C				Not Reported
	Pip/Tazo 3.375 Gm Q6h			C				Not Reported
	Linezolid 600 Mg Iv Q12h			C				Not Reported
	Kcl 40 Meq X 4 Doses			C				Not Reported
	Vancomycin 1 Gm X One Dose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18396933	DIRECT	Y				54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18396936	DIRECT	Y				81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Administration Site Extravasation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2020	18396968	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Albumin 25%			C				Not Reported
	Albuterol Nebulizer			C				Not Reported
	Aspirin			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Dexamethasone			C				Not Reported
	Digoxin			C				Not Reported
	Enoxaparin			C				Not Reported
	Epoprostenol Inhaled			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Furosemide			C				Not Reported
	Heparin Infusion			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Ipratropium/Albuterol Nebulized			C				Not Reported
	Norepinephrine			C				Not Reported

		Piperacillin/Tazobactam			C					Not Reported
		Vancomycin			C					Not Reported
		Propofol			C					Not Reported
		Rocuronium Infusion			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18077932	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0485701		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Acute Kidney Injury; Alanine Aminotransferase Increased; Anaemia; Arrhythmia; Arrhythmia Supraventricular; Cardio-Respiratory Arrest; Decubitus Ulcer; Hyponatraemia; Hypotension; Leukocytosis; Normochromic Normocytic Anaemia; Pneumonia Bacterial; Sepsis Syndrome; Shock; Staphylococcal Infection	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Piperacillin And Tazobactam			C		Unk		Not Reported
	Piperacillin And Tazobactam			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Zinc Gluconate			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Vitamin C Flavour			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Rocuronium			C		Unk		Not Reported
	Human Albumin			C		Unk		Not Reported
	Sodium Phosphate			C		Unk		Not Reported
	Calcium Gluconate			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Quetiapine			C				Not Reported
	Midazolam			C		Unk		Not Reported
	Fluconazole			C		Unk		Not Reported

Telavancin	C	Unk	Not Reported
Insulin Glargine	C	Unk	Not Reported
Insulin Glargine	C		Not Reported
Sodium Bicarbonate	C	Unk	Not Reported
Ketamine	C	Unk	Not Reported
Ceftriaxone	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Albuterol Hfa	C	Unk	Not Reported
Insulin Lispro	C		Not Reported
Insulin Lispro	C		Not Reported
Micafungin	C	Unk	Not Reported
Magnesium Sulfate	C	Unk	Not Reported
Potassium Chloride	C	Unk	Not Reported
Epoprostenol	C	Unk	Not Reported
Duoneb	C	Unk	Not Reported
Cisatracurium	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Kayexalate	C	Unk	Not Reported
Collagenase	C	Unk	Not Reported
Dexamethasone Sodium Phosphate	C	Unk	Not Reported
Miconazole	C	Unk	Not Reported
Alprazolam	C	Unk	Not Reported
Hydrocortisone Sodium Succinate	C	Unk	Not Reported
Nexterone	C	Unk	Not Reported
Pacerone	C	Unk	Not Reported
Nozin Nasal Sanitizer	C	Unk	Not Reported
Arformoterol	C	Unk	Not Reported
Pulmicort	C	Unk	Not Reported
Argatroban	C	Unk	Not Reported
Metoclopramide	C		Not Reported

Hydralazine	C		Not Reported
Prosource Tf	C	Unk	Not Reported
Bisacodyl	C	Unk	Not Reported
Chlorhexidine	C	Unk	Not Reported
Phenylephrine	C	Unk	Not Reported
Adenosine	C	Unk	Not Reported
Metoprolol	C	Unk	Not Reported
Cerovite	C	Unk	Not Reported
Etomidate	C	Unk	Not Reported
Etomidate	C		Not Reported
Glucerna Therapeutic Nutrition	C	Unk	Not Reported
Ascorbic Acid	C	Unk	Not Reported
Potassium Phosphates	C	Unk	Not Reported
Phosphorus	C	Unk	Not Reported
Sodium Phosphates [Sodium Phosphate]	C	Unk	Not Reported
Ondansetron	C	Unk	Not Reported
Ondansetron	C		Not Reported
Promethazine	C	Unk	Not Reported
Promethazine	C		Not Reported
Nicotine	C		Not Reported
Iohexol	C	Unk	Not Reported
Hydrocodone	C	Unk	Not Reported
Glucagon	C	Unk	Not Reported
Rocephine	C	Unk	Not Reported
Azithromycin	C	Unk	Not Reported
Acetaminophen	C	Unk	Not Reported
Sodium Lactate Ringer'S	C	Unk	Not Reported
Plasma	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18270868	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0494950		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Oxygen			C				Not Reported
	Insulin			C				Not Reported
	Haloperidol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18325467	EXPEDITED (15-DAY)		HO, OT	ES-VIIV HEALTHCARE LIMITED-ES2020GSK190087		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Maraviroc			S	Oral	300 Mg, Bid		Viiv
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Glaxosmithkline
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18327175	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0496553		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Metoprolol			S	Oral	50 Mg, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg, Bid		Not Reported
	Losartan			C				Not Reported
	Multivitamins [Vitamins Nos]			C	Oral	Unk		Not Reported

	Guaifenesin/Codeine			C		5 Ml, Prn				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18397702	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Headache; Infusion Related Reaction; Liver Function Test Increased	Remdesivir 200mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Zosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18397744	DIRECT	Y	DS, OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead
	Hydrochlorothiazide			C				Not Reported
	Losartan			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Tamsulosin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18397773	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Wrong Product Administered	Remdesivir			S	Intravenous drip	Other Frequency:Not Scheduled;		Gilead
	Fentanyl 2500mcg/Ml Gtt			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18397782	DIRECT	Y	HO			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Zinc			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecaliciferol			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Sucralfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18397830	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18397938	DIRECT	Y	OT			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18397943	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18397978	DIRECT	Y	DE			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Acute Respiratory Failure; Haemodialysis; Pulmonary Fibrosis; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Pipericillin- Tazobactim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398118	DIRECT	Y	LT, OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Kidney Injury; Hypovolaemia	Remdesivir			S				Gilead
	Azithromycin Injection			C				Not Reported
	Ceftriaxone Injection			C				Not Reported
	Dexamethasone Tablet/Injection			C				Not Reported
	Enoxaparin			C				Not Reported
	Ezetimibe Tablet			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lidocaine 5% Patch			C				Not Reported
	Loperamide Capsule			C				Not Reported
	Morphine Injection			C				Not Reported
	Diphenhydramine/Acetaminophen Tablet			C				Not Reported
	Acetaminophen Tablet			C				Not Reported
	Ondansetron Injection			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398266	DIRECT	Y	DE			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoxia; Sars-Cov-2	Remdesivir			S	Intravenous bolus			Gilead

Antibody Test Positive

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398473	DIRECT	Y	DE			96 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure; Thrombocytopenia	Inv-Remdesivir (Inv-Remdesivir 5mg/Ml Inj, Soln M)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398560	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir (Eau)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398588	DIRECT	Y	DE			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Cardiac Failure; Cardio-Respiratory Arrest; Coronary Artery Disease; Ejection Fraction Decreased; Hypertension	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albumin			C				Not Reported
	Amiodarone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine Gluconate			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline Hyclate			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl Citrate			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lactobacillus Acidoph/Bulgar			C				Not Reported
	Lorazepam			C				Not Reported

		Melatonin			C					Not Reported
		Propofol			C					Not Reported
		Sodium Polystyrene Sulfonate			C					Not Reported
		Tamsulosin			C					Not Reported
		Vecuronium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398600	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Heart Rate Increased; Therapy Interrupted	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398612	DIRECT	Y	OT			18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Loading Dose (Once;		Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398625	DIRECT	Y	OT			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398630	DIRECT	Y	OT			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398759	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398763	DIRECT	Y	OT			31 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398788	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398877	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398882	DIRECT	Y	OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398892	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398894	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398922	DIRECT	Y	OT			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398931	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398966	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Melatonin			C				Not Reported
	Dexomethorphan Guaifenesin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Montelukast			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398970	DIRECT	Y	OT			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398975	DIRECT	Y	DE, LT, OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardio-Respiratory Arrest; Pulseless Electrical Activity	Remdesivir	Y		S	Intravenous (not otherwise specified)			Amerisource Bergen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18398981	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18399107	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18399110	DIRECT	Y	OT			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18399117	DIRECT	Y	OT			82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18401141	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0499454		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18401180	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0499461		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Infusion Site Swelling	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Acetaminophen			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Zinc Sulphate			C		Unk		Not Reported
	Thiamine			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18401210	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0499804		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Guaifenesin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

	Benzonatate			C		Unk				Not Reported
	Pregabalin			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18402569	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0498985		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once; Loading Dose (D5)		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd, (D6-D9)		Gilead
	Dexamethasone			C				Not Reported
	Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18402765	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0499451		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18402790	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0499713		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukocytosis; Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Citalopram			C				Not Reported
	Fluticasone			C				Not Reported
	Levothyroxine			C				Not Reported
	Spironolactone			C				Not Reported

	Warfarin			C						Not Reported
	Hydroxyzine			C						Not Reported
	Lorazepam			C						Not Reported
	Ondansetron			C			Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18402807	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0499803		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extravasation; Infusion Site Oedema; Infusion Site Swelling	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Metoprolol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18402809	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0499739		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiopulmonary Failure; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S				Gilead
	Epinephrine			C				Not Reported
	Bicarbonate			C				Not Reported
	Calcium			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Pantoprazole			C				Not Reported
	Petrolatum			C				Not Reported
	Heparin			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18402907	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468930		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Peripheral Swelling	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18403335	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18403343	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18403350	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18403366	DIRECT		HO			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Chest Pain; Dyspnoea; Nausea; Tremor;	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported
	Amiodarone			C				Not Reported

Ventricular Extrasystoles	Aspirin			C					Not Reported
	Rocephin			C					Not Reported
	Zyrtec			C					Not Reported
	Plavix			C					Not Reported
	Lovenox			C					Not Reported
	Gabapentin			C					Not Reported
	Insulin Lispro			C					Not Reported
	Zofran			C					Not Reported
	Protonix			C					Not Reported
	Tramadol			C					Not Reported
	Magnesium Oxide			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18403377	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Injection, Lyophilized Powder	Y		S	Intravenous bolus	Other Frequency:Once (Loading Dose;		Gilead
	Morphine Inj 2 Mg			C				Not Reported
	Ofirmev 1000 Mg			C				Not Reported
	Robitussin Dm 10 Ml			C				Not Reported
	Benzonatate 100 Mg			C				Not Reported
	Dexamethasone 6 Mg Inj			C				Not Reported
	Meropenem 1 G			C				Not Reported
	Acetaminophen 650 Mg			C				Not Reported
	Metoclopramide 10 Mg Inj			C				Not Reported
	Norco 10/325 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2020	18403383	DIRECT	Y				37 YR	Male	GUM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500mg			C				Not Reported
	Ceftriaxone 1g			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18312579	EXPEDITED (15-DAY)		OT	ES-VIIV HEALTHCARE LIMITED-ES2020GSK188433		89 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia	Maraviroc			S		Unk Unk, Bid		Viiv
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Glaxosmithkline
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18403796	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18403868	DIRECT	Y	OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Asthenia	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18403908	DIRECT	Y	DE			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspnoea; Hypoxia	Remdesivir		S	Intravenous bolus		Gilead
	Dexamethasone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404222	DIRECT	Y				43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404334	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404388	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:Iv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404465	DIRECT	Y	RI			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

Increased; Hepatic Enzyme Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404504	DIRECT	Y				81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404583	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Zyvox			C				Not Reported
	Cefazolin			C				Not Reported
	Cephalexin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404590	DIRECT	Y	RI			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404693	DIRECT	Y	RI			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404770	DIRECT	Y	DE, RI, OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404828	DIRECT	Y				39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol-Ipratropium			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Ketamine			C				Not Reported
	Levothyroxine			C				Not Reported
	Lidocaine			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported

Polyethylene Glycol 3350	C		Not Reported
Potassium Phosphate	C		Not Reported
Propofol	C		Not Reported
Senna	C		Not Reported
Tocilizumab	C		Not Reported
Vancomycin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404858	DIRECT	Y	OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18404949	DIRECT	Y				36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Feeling Jittery; Flushing; Psychomotor Hyperactivity	Remdesivir			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18405009	DIRECT	Y	DE			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; General Physical Health Deterioration; Thrombectomy; Transient Ischaemic Attack	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18405067	DIRECT	Y				60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18405198	DIRECT	Y				72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18405407	DIRECT	Y	OT			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hypoperfusion; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Lexapro			C				Not Reported
	Tocilizumab			C				Not Reported
	Atorvastatin			C				Not Reported
	Dronedarone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Torsemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18405408	DIRECT	Y	OT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity;	Remdesivir			S	Intravenous (not	Other Frequency:Once;		Gilead

Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged				otherwise specified)	
	Remdesivir	S	Intravenous (not otherwise specified)		Gilead
	Methylprednisolone	C			Not Reported
	Diltiazem	C			Not Reported
	Zinc Sulfate	C			Not Reported
	Enoxaparin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18405410	DIRECT	Y	OT			49 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18405545	DIRECT	Y				75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18405563	DIRECT	Y	DE			91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration;	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

Thrombocytopenia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18406189	EXPEDITED (15-DAY)			US-GILEAD-2020-0500159			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue	Remdesivir			S	Unknown			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18408294	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0500134		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Zosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18408651	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0500158		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Metoprolol Tartrate			C		Unk		Not Reported
	Tamsulosin			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18409000	DIRECT	Y	OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2020	18409008	DIRECT	Y	OT			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18330764	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0496822		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Large Intestine Perforation	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C	Intravenous (not otherwise specified)	800 Mg		Not Reported
	Albuterol Inhaler			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin Ec			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone Sodium			C				Not Reported
	Enoxaparin			C				Not Reported
	Gabapentin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Insulin Glargine			C				Not Reported

	Insulin Lispro	C			Not Reported
	Insulin Regular	C		Sliding Scale	Not Reported
	Lisinopril	C			Not Reported
	Magnesium Oxide	C			Not Reported
	Metformin	C			Not Reported
	Metoprolol	C			Not Reported
	Ondansetron	C			Not Reported
	Potassium Chloride	C			Not Reported
	Sodium Chloride 0.9%	C			Not Reported
	Zinc Sulfate	C			Not Reported
	Zosyn	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18384521	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0498632		85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C	Oral	6 Mg		Not Reported
	Albuterol [Salbutamol Sulfate]			C	Respiratory (inhalation)	180 Mcg		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Oral	81 Mg, Qd		Not Reported
	Cholecalciferol			C	Oral	Unk		Not Reported
	Heparin			C	Subcutaneous	Unk		Not Reported
	Ipratropium			C	Respiratory (inhalation)	2 Puffs		Not Reported
	Miralax			C	Oral	17 G		Not Reported
	Tamsulosin			C	Oral	0.4 Mg		Not Reported
	Timolol			C	Ophthalmic	1 Dosage Form		Not Reported

	Vancomycin	C		1250 Mg		Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	2000 Mg		Not Reported
	Cefuroxime	C	Oral	500 Mg		Not Reported
	Cefuroxime	C				Not Reported
	Mirtazapine	C	Oral	15 Mg		Not Reported
	Senna [Senna Alexandrina]	C	Oral	8.6 Mg		Not Reported
	Alprazolam	C	Oral	0.25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18408290	EXPEDITED (15-DAY)		DE, HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-264396		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchopleural Fistula; Disease Progression; Empyema; Respiratory Failure; Septic Shock	Azithromycin			S	Unknown	Unk		Sun
	Dexamethasone			S	Unknown	Unk		Sun
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Enoxaparin Sodium			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18410040	DIRECT	Y				82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Interrupted	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18410207	DIRECT	Y				59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18410217	DIRECT	Y	OT			51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18410374	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead
	Amlodipine 5 Mg Po			C				Not Reported
	Dexamethasone 6 Mg Po			C				Not Reported
	Benzonatate 200 Mg Po			C				Not Reported
	Aspirin 81 Mg Po			C				Not Reported
	Acetaminophen 650 Mg Po			C				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported
	Ceftriaxone 1000 Mg Iv			C				Not Reported
	Heparin 5000 Unit Sq			C				Not Reported
	Potassium Chloride 40 Meq Po			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18410740	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1088247		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Ceftriaxone			S	Intravenous (not otherwise specified)	100 Milliliter, Qd		Mylan
	Ivermectin			S	Oral	18 Milligram, Qd		Not Reported

Enoxaparin	S	Subcutaneous	1000 International Unit, Bid		Mylan
Dexamethasone	S	Intramuscular	6 Milligram, Qd		Mylan
Remdesivir	S	Intravenous (not otherwise specified)	200mg On D1 Then 100mg D2 To D5		Mylan
Paracetamol	S	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan
Paracetamol	S	Intravenous (not otherwise specified)	1 Gram, Q8h		Mylan
Diffu K	C		Unk		Mylan
Rocephine	C	Intravenous (not otherwise specified)	Unk		Mylan
Bisoprolol	C		Unk		Mylan
Oxygen	C		Unk		Mylan
Rovamycine /00074401/	C	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18410748	DIRECT	Y	OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir Eua			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18410781	DIRECT	Y	DE			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 6mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18413201	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0500243		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Assist Device Therapy	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18413217	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0500320		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead
	Zinc			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Sucralfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18413240	EXPEDITED (15-DAY)			US-GILEAD-2020-0500340			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Preparation Issue	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18414260	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Eye Movement Disorder; Therapy Cessation	Remdesivir	Y	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18414266	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bradycardia; Hypertension	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18414303	DIRECT	Y	OT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Albuterol Inhaled			C				Not Reported
	Budesonide/Formoterol Inhaled			C				Not Reported
	Escitalopram			C				Not Reported
	Clopidogrel			C				Not Reported
	Amiodarone			C				Not Reported
	Aspirin			C				Not Reported
	Montelukast			C				Not Reported
	Dexamethasone			C				Not Reported
	Pantoprazole			C				Not Reported
	Pregabalin			C				Not Reported
	Furosemide			C				Not Reported
	Acetylcysteine Inhaled			C				Not Reported
	Ipratropium/Albuterol Inhaled			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Glargine			C				Not Reported
	Vasopressin			C				Not Reported
	Propofol			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported
	Norepinephrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2020	18414733	DIRECT	Y				86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Infusion Site Discomfort; Infusion Site Erythema; Infusion Site Induration	Remdesivir 100mg/250ml Norm. Saline			S				Not Reported
	Pantoprazole			C				Not Reported
	Dexamethasone			C				Not Reported
	Amlodipine			C				Not Reported
	Tamulosin			C				Not Reported
	Metoprolol			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Lovenox			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18232169	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0493328		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Death; Hepatitis B Surface Antigen Positive; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Doxycycline			C		Unk		Not Reported
	Fentanyl			C		Titrate		Not Reported
	Piperacillin & Tazobactam			C		Unk		Not Reported
	Vasopressin			C		Unk		Not Reported
	Propofol			C		Titrate		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18352374	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0497536		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Endotracheal Intubation; Oxygen Saturation Decreased; Rash; Respiratory Distress; Somnolence; Troponin Increased; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Insulin Detemir			C	Subcutaneous	Sliding Scale		Not Reported
	Acetaminophen			C	Oral	65 Mg		Not Reported
	Dexamethasone			C	Oral	6 Mg		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Piperacillin & Tazobactam			C	Intravenous (not otherwise specified)	4.5 Mg		Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Insulin Aspart			C	Subcutaneous	Sliding Scale		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18414806	DIRECT	Y	OT			89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18414840	DIRECT	Y	DE			96 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18414917	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Wrong Technique In Product Usage Process	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18414930	DIRECT	Y				66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Wrong Technique In Product Usage Process	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415025	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Bilirubin Conjugated Increased; Blood Alkaline Phosphatase Increased; Hepatitis; International Normalised Ratio Increased; Renal Replacement Therapy; Septic Shock; Shock	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415027	DIRECT	Y				95 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Cardio-Respiratory Arrest; Creatinine Renal Clearance Decreased; Hypoxic-Ischaemic Encephalopathy	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415125	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415147	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Duloxetine			C				Not Reported
	Escitalopram			C				Not Reported
	Ezetimibe			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported

Insulin Aspart	C		Not Reported
Insulin Glargine	C		Not Reported
Liraglutide	C		Not Reported
Metoprolol	C		Not Reported
Ramipril	C		Not Reported
Warfarin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415296	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07617		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415314	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07618		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415334	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not			Not Reported

						otherwise specified)				
		Acetaminophen			C					Not Reported
		Dexamethasone			C					Not Reported
		Enoxaparin			C					Not Reported
		Ceftazidime			C					Not Reported
		Famotidine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415347	DIRECT	Y	LT			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Therapy Cessation; Ventricular Extrasystoles	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin 20 Mg Daily			C				Not Reported
	Azithromycin 500mg Daily			C				Not Reported
	Ceftriaxone 1 Gm Daily			C				Not Reported
	Clopidogrel 75 Mg Daily			C				Not Reported
	Dexamethasone 6mg Daily			C				Not Reported
	Enoxaparin 40mg Daily			C				Not Reported
	Finasteride 5 Mg Daily			C				Not Reported
	Levothyroxine 25 Mcg Daily			C				Not Reported
	Tamsulosin 0.4 Mg Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415351	DIRECT	Y				87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia; Expired Product Administered; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415367	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07619		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine		S	Unknown	Unk	Lupin
	Remdesivir		S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remdesivir		S	Intravenous (not otherwise specified)	100 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415377	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07620		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415401	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07621		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415498	DIRECT	Y				54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18415621	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18416414	EXPEDITED (15-DAY)		LT, OT	DE-MYLANLABS-2020M1088666		70 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hepatotoxicity; Hypoalbuminaemia; Hypotension	Klacid			S	Intravenous (not otherwise specified)	500 Milligram, Bid		Mylan
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd, (1x Täglich)		Mylan
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram, Total (200mg In 250mg Nacl Uber 2 Stunden Initial, Danach 100mg Uber 2 Stunden)		Mylan
	Unacid /00917901/			S	Intravenous (not otherwise specified)	3 Gram, Q8h		Mylan
	Propofol			C	Intravenous (not otherwise specified)	10 Mg/Ml		Mylan
	Propofol			C				Mylan
	Sufentanil			C	Intravenous (not otherwise specified)	0.015 Mg/Ml		Mylan
	Sufentanil			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18417139	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0500562		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Oxygen			C					Not Reported
	Dexamethasone			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18417142	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0500550		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Asthenia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18417775	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0500624		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Amlodipine			C				Not Reported
	Dexamethasone			C				Not Reported
	Benzonatate			C				Not Reported
	Aspirin 81			C				Not Reported
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Heparin			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18418763	DIRECT	Y	DE			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18418770	DIRECT	Y	DE			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18418777	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palliative Care	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18418797	DIRECT	Y				60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Refusal Of Treatment By Patient; Wrong Technique In Product Usage Process	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Aspirin Ec 81 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Calcitriol 0.25 Mcg			C				Not Reported
	Rocephin 2000 Mg			C				Not Reported
	Dexamethsone 6 Mg			C				Not Reported
	Lovenox 60 Mg/0.6 Ml			C				Not Reported
	Heparin 60 Mg Bolus			C				Not Reported
	Heparin In D5w 9ml/Hr			C				Not Reported
	Heparin In D5w 2.8-25.3ml/Hr			C				Not Reported
	Humalog 1-6 Units			C				Not Reported

	Humalog 1-3			C					Not Reported
	Losartan 100 Mg			C					Not Reported
	Metoprolol Succinate 100 Mg			C					Not Reported
	Ondansetron 4 Mg			C					Not Reported
	Melatonin 3 Mg			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2020	18419014	DIRECT	Y	OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Not Reported
	Furosemide			C				Not Reported
	Iohexol			C				Not Reported
	Azithromycin			C				Not Reported
	Budesonide-Formoterol Inhaled			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18306911	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-ROCHE-2677271		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Acute Kidney Injury; Covid-19 Pneumonia; Pneumonia	Tocilizumab			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose Of Tocilizumab (100 Ml) Prior To Ae Onset: 11/Sep/2020		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Most Recent Dose Of Remdesvir Prior To Ae/Sae Onset On 10/Sep/2020 At 20:53 Hours.		Not Reported
	Lovenox			C				Not Reported
	Lovenox			C				Not Reported
	Human Insulin			C				Not Reported
	Human Insulin			C				Not Reported

Solumedrol	C			Not Reported
Solumedrol	C			Not Reported
Zofran	C			Not Reported
Protonix (United States)	C			Not Reported
Omeprazole	C			Not Reported
Famotidine	C			Not Reported
Acetaminophen	C			Not Reported
Acetaminophen	C			Not Reported
Dextrose In Water	C			Not Reported
Diphenhydramine	C			Not Reported
Glucagon	C			Not Reported
Lantus	C			Not Reported
Lantus	C		50 Units	Not Reported
Humalog	C			Not Reported
Methylprednisolone	C			Not Reported
Alteplase	C	Intravenous (not otherwise specified)		Not Reported
Hypromellose	C			Not Reported
Hypromellose	C			Not Reported
Chlorhexidine Gluconate	C			Not Reported
Cisatracurium	C			Not Reported
Cisatracurium	C			Not Reported
Cisatracurium	C		2.5 Other	Not Reported
Cisatracurium	C		1.5 Other	Not Reported
Cisatracurium	C		3 Other	Not Reported
Clonazepam	C			Not Reported
Dexmedetomidine	C			Not Reported
Dexmedetomidine	C			Not Reported
Dexmedetomidine	C			Not Reported
Dobutamine	C			Not Reported
Dobutamine	C			Not Reported
Epinephrine	C			Not Reported
Epinephrine	C			Not Reported
Fentanyl	C			Not Reported
Fentanyl	C		Dose: 50 Other	Not Reported
Haloperidol Lactate	C			Not Reported
Heparin	C		1800 Units	Not Reported
Heparin	C		Dose: 1500 Unit	Not Reported

	Lactated Ringers	C	50 Units	Not Reported
	Lactated Ringers	C		Not Reported
	Lorazepam	C		Not Reported
	Lorazepam	C		Not Reported
	Midazolam	C		Not Reported
	Norepinephrine	C		Not Reported
	Piperacillin;Tazobactam	C		Not Reported
	Propofol	C		Not Reported
	Propofol	C		Not Reported
	Sodium Bicarbonate	C		Not Reported
	Sodium Chloride	C		Not Reported
	Sodium Chloride	C		Not Reported
	Sodium Chloride	C		Not Reported
	Vancomycin	C		Not Reported
	Vancomycin	C		Not Reported
	Vancomycin	C		Not Reported
	Vasopressin	C		Not Reported
	Vasopressin	C		Not Reported
	White Petrolatum	C	Mineral Oil	Not Reported
	Calcium Gluconate	C		Not Reported
	Sodium Citrate	C		Not Reported
	Sennosides	C		Not Reported
	Rocuronium	C		Not Reported
	Polyethylene Glycol	C		Not Reported
	Docusate	C		Not Reported
	Bisacodyl	C		Not Reported
	Cefepime	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18392331	EXPEDITED (15-DAY)		OT	IT-ROCHE-2693167		38 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Off Label Use; Pancreatitis	Veklury			S	Intravenous (not otherwise specified)	Last Dose Received On 12/Apr/2020		Not Reported
	Tocilizumab			S	Subcutaneous	162 Mg		Not Reported
	Lopinavir;Ritonavir			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18418498	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07751			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Remdesivir			S	Transplacental	200 Milligram		Not Reported
	Remdesivir			S	Transplacental	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18418506	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07726			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Remdesivir			S	Transplacental	200 Milligram		Not Reported
	Remdesivir			S	Transplacental	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18418516	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07734			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Remdesivir			S	Transplacental	200 Milligram		Not Reported
	Remdesivir			S	Transplacental	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18418523	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-07748			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine	S	Transplacental	Unk		Lupin
	Remdesivir	S	Transplacental	200 Milligram		Not Reported
	Remdesivir	S	Transplacental	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18419225	DIRECT	Y	OT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Cefepime			C				Not Reported
	Pantoprazole			C				Not Reported
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18419573	DIRECT	Y	OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Menorrhagia	Remdesivir			S				Not Reported
	Azithromycin			C				Not Reported
	Carvedilol			C				Not Reported
	Dexamethasone			C				Not Reported
	Loratadine			C				Not Reported
	Tamoxifen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18419849	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported
	Levothyroxine			C				Not Reported
	Enoxaparin			C				Not Reported
	Amlodipine			C				Not Reported
	Levothyroxine			C				Not Reported

	Losartan			C						Not Reported
	Paroxetine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18420466	DIRECT	Y	DE			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactate Dehydrogenase Increased; C-Reactive Protein Increased; Confusional State; Delirium; Pulmonary Function Test Decreased; Respiratory Failure; Serum Ferritin Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18420484	EXPEDITED (15-DAY)			US-GILEAD-2020-0500812			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18420510	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Expired Product Administered	Remdesivir	Y		S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18420553	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0500644		81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Extravasation	Remdesivir			S	Intravenous (not otherwise specified)				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18420856	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0500641		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Remdesivir			S	Unknown			Gilead
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2020	18422226	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0501199		96 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2020	18425173	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2020	18425177	DIRECT	Y				70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Pain In Extremity; Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time Only;		Gilead

		Norco 5-325mg			C					Not Reported
		Dexamethasone 6mg			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2020	18425186	DIRECT	Y	DE, OT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2020	18425198	DIRECT	Y				38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Fenofibrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2020	18425201	DIRECT	Y				58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Toxicity To Various Agents	Remdesivir	Y		S	Intravenous drip	Other Frequency:Loading Dose;		Modernatx
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2020	18425206	DIRECT	Y				20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate	Eua Remdesivir			S	Intravenous (not			Gilead

Aminotransferase Increased; Hepatic Enzyme Increased				otherwise specified)		
	Decadron	C				Not Reported
	Pepcid	C				Not Reported
	Tylenol	C				Not Reported
	Enoxaparin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18082674	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485073		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Rocephin [Ceftriaxone Sodium]			C		Unk		Not Reported
	Rocephin [Ceftriaxone Sodium]			C		Unk		Not Reported
	Zosyn			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18257315	EXPEDITED (15-DAY)		DE, HO, LT	BR-ROCHE-2657395		55 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atelectasis; Pneumonia Klebsiella; Post Procedural Haemorrhage; Respiratory Failure; Sepsis	Tocilizumab			S	Intravenous (not otherwise specified)	The Most Recent Dose Of Tocilizumab (100 Ml) Prior To Onset Of Ae And Sae Was On 22/Jul/2020 At 20:1		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	The Most Recent Dose Of Remdesivir (100 Ml) Prior To Ae And Sae Onset Was On 31/Jul/2020 At 15:36		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18322292	EXPEDITED (15-DAY)		DE, LT	BR-ROCHE-2681808		20 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Obstructive Shock; Pneumonia; Pneumothorax; Septic Shock	Tocilizumab			S	Intravenous (not otherwise specified)	On 03/Sep/2020, At 09:39 Most Recent Dose Of Blinded Tocilizumab Was Administered Prior To Adverse E		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	On 11/Sep/2020, At 15:15 Most Recent Dose Of Intravenous Remdesivir (100 Ml) Prior To Adverse Event		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18425316	EXPEDITED (15-DAY)			US-GILEAD-2020-0501209		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18425436	EXPEDITED (15-DAY)			US-GILEAD-2020-0501207		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18425533	EXPEDITED (15-DAY)		DE, HO	JP-MYLANLABS-2020M1088437		76 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Gastrointestinal Haemorrhage; Hypernatraemia; Hypotension; Insomnia; Pneumothorax; Subcutaneous Emphysema	Magnesium Oxide			S	Unknown			Mylan
	Sennoside			S	Unknown			Not Reported
	Pitressin /01872201/			S	Unknown			Mylan
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram, Qd		Mylan
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd		Mylan
	Rozerem			S	Oral	Unk		Mylan
	Belsomra			S	Oral	Unk		Mylan
	Reslin			S	Unknown			Mylan
	Red Blood Cells-Leukocytes Reduced			S	Unknown			Mylan
	Fresh Frozen Plasma			S	Unknown			Mylan
	Adona /00056903/			S	Unknown			Mylan
	Transamin			S	Unknown			Mylan
	Predonine /00016204/			C	Unknown	Unk		Mylan
	Pydoxal			C	Unknown	Unk		Mylan
	Gluconsan K			C	Unknown	Unk		Mylan
	Ampicillin Sodium And Sulbactam Sodium			C	Unknown	Unk		Mylan
	Piperacillin Sodium			C	Unknown	Unk		Mylan
	Azithromycin /00944303/			C	Unknown	Unk		Mylan
	Gaster /00706001/			C	Unknown	Unk		Mylan
	Amlodipine			C	Unknown	Unk		Mylan
	Kcl			C	Unknown	Unk		Mylan
	Bisolvon			C	Unknown	Unk		Mylan

	Heparin	C	Unknown	Unk		Mylan
	Propofol	C	Unknown	Unk		Mylan
	Noradrenalin /00127502/	C	Unknown	Unk		Mylan
	Alfarol	C	Unknown	Unk		Mylan
	Dexmedetomidine	C	Unknown	Unk		Mylan
	Fentanyl	C	Unknown	Unk		Mylan
	Daiphen	C	Unknown	Unk		Mylan
	Lansoprazole	C	Unknown	Unk		Mylan
	Ezetimibe	C	Unknown	Unk		Mylan
	Livalo	C	Unknown	Unk		Mylan
	Cilostazol	C	Unknown	Unk		Mylan
	Iscotin /00030201/	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18425935	DIRECT	Y				64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported
	Magnesium Oxide			C				Not Reported
	Albuterol			C				Not Reported
	Acetaminophen			C				Not Reported
	Calcium Carbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18425948	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18426014	DIRECT					69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18426219	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 6 Mg Po Daily			C				Not Reported
	Enoxaparin 40 Mg Sq Daily			C				Not Reported
	Guaifenesin 600 Mg Sr Bid			C				Not Reported
	Heparin 5000 Units Sq Q8h			C				Not Reported
	Acetaminophen 650 Mg Po Q4h Prn			C				Not Reported
	Alprazolam 0.25 Mg Po Q6h Prn			C				Not Reported
	Benzonatate 200 Mg Po Tid Prn			C				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18426373	DIRECT	Y				92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Fatigue; Feeling Abnormal; Labile Hypertension; Malaise; Therapy Cessation	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported
	Sodium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18426391	DIRECT	Y	HO, OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Steatosis; International Normalised Ratio Increased; Nausea	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Lisinopril			C				Not Reported
	Multiple Vitamin			C				Not Reported
	Pantoprazole			C				Not Reported
	Metoclopramide			C				Not Reported
	Ondansetron			C				Not Reported
	Oxycodone			C				Not Reported
	Tizanidine			C				Not Reported
	Lactated Ringers			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18426600	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported
	Sinemet			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Folic Acid			C				Not Reported
	Humalog			C				Not Reported
	Latanoprost			C				Not Reported
	Flagyl			C				Not Reported
	Midodrine			C				Not Reported
	Montelukast			C				Not Reported
	Multivitamin			C				Not Reported
	Mupirocin			C				Not Reported
	Protonix			C				Not Reported
	Miralax			C				Not Reported
	Thiamine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18426650	DIRECT	Y	DE			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Heart Rate Increased; Incorrect Dose Administered; Oxygen Saturation Decreased; Pneumonia Bacterial; Refusal Of Treatment By Patient; Respiratory Failure; Respiratory Rate Increased; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Methylprednisolone			C				Not Reported
	Duoneb			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18426888	DIRECT	Y				94 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Albuterol Inhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18426913	DIRECT	Y				67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18426978	DIRECT	Y				75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

	Amantadine			C					Not Reported
	Aspirin			C					Not Reported
	Dexamethasone			C					Not Reported
	Enoxaparin			C					Not Reported
	Ferrous Sulfate			C					Not Reported
	Latanoprost Ophthalmic			C					Not Reported
	Levetiracetam			C					Not Reported
	Levothyroxine			C					Not Reported
	Memantine			C					Not Reported
	Miconazole			C					Not Reported
	Olanzapine			C					Not Reported
	Polyethylene Glycol 3350			C					Not Reported
	Tamsulosin			C					Not Reported
	Lorazepam			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18427580	DIRECT	Y				56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18427585	DIRECT	Y	OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Ischaemic Hepatitis	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18427616	DIRECT	Y				88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Ampicillin Sulbactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18427623	DIRECT	N	OT			34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amlodipine Besylate			C				Not Reported
	Apixaban			C				Not Reported
	Atorvastatin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18429531	EXPEDITED (15-DAY)			US-GILEAD-2020-0497170		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error; Product Temperature Excursion Issue	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18429700	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0501216		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Blood Bilirubin Increased; International Normalised Ratio Increased; Sepsis; Septic	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

Shock

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18429728	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0501205		86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Expired Product Administered; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18429729	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0501211		95 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Apnoeic Attack; Areflexia; Death; Endotracheal Intubation; Extubation; Hypoxic-Ischaemic Encephalopathy; Mechanical Ventilation; Pulse Absent	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Insulin			C		Sliding Scale		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18429843	EXPEDITED (15-DAY)		LT	US-GILEAD-2020-0501193		86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Ventricular Extrasystoles	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin			C		20 Mg, Qd		Not Reported
	Azithromycin			C		500 Mg, Qd		Not Reported

Ceftriaxone	C	1 G, Qd	Not Reported
Clopidogrel	C	75 Mg, Qd	Not Reported
Dexamethasone	C	6 Mg, Qd	Not Reported
Enoxaparin	C	40 Mg, Qd	Not Reported
Finasteride	C	5 Mg, Qd	Not Reported
Levothyroxine	C	25 Mcg Qd	Not Reported
Tamsulosin	C	0.4 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18430573	DIRECT	Y	DE				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18430580	DIRECT	Y				74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir Lyophilized Powder			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2020	18430591	DIRECT	Y	OT			74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation; Infusion Site Oedema; Oedema	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18143304	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0489774		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Covid-19; General Physical Health Deterioration; Pneumonia Staphylococcal	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18310098	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0496218		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Oxygen			C				Not Reported
	Epoprostenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18430742	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020413580		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Product Use In Unapproved Indication; Pruritus; Rash Maculo-Papular	Azithromycin			S		Unk		Pfizer
	Lopinavir/Ritonavir			S		Unk		Not Reported
	Interferon Beta			S		Unk		Not Reported
	Ceftriaxone			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Dextromethorphan			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Remdesivir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18431207	DIRECT	Y				58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Metoprolol (Lopressor)			C				Not Reported
	Furosemide (Lasix)			C				Not Reported
	Acetaminophen			C				Not Reported
	Iohexol (Omnipaque)			C				Not Reported
	Dexmedetomidine (Precedex)			C				Not Reported
	Midazolam (Versed)			C				Not Reported
	Enoxaparin			C				Not Reported
	Cisatracurium (Nimbex)			C				Not Reported
	Fentanyl (Sublimaze)			C				Not Reported
	Pantoprazole (Protonix)			C				Not Reported
	Piperacillin-Tazobactam (Zosyn)			C				Not Reported
	Dexamethasone			C				Not Reported
	Vancomycin			C				Not Reported
	Heparin			C				Not Reported
	Sennosides			C				Not Reported
	Docusate			C				Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18431302	DIRECT	Y	OT			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Dexamethasone			C				Not Reported
	Atorvastatin			C				Not Reported
	Aspirin			C				Not Reported
	Enoxaparin			C				Not Reported
	Iohexol Contrast			C				Not Reported
	Tocilizumab			C				Not Reported
	Furosemide			C				Not Reported

	Insulin Lispro			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18431461	DIRECT	Y				69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18431577	DIRECT	Y	HO, LT, OT			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Malaise	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Albuterol			C				Not Reported
	Amiodarone			C				Not Reported
	Budesonide/Formoterol			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Citrate Phosphate Dextrose			C				Not Reported
	Dexamethasone			C				Not Reported
	Diltiazem			C				Not Reported
	Epinephrine			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Linezolid			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone			C				Not Reported
	Norepinephrine			C				Not Reported
	Phenylephrine			C				Not Reported
	Vancomycin			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18431757	DIRECT	Y	OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18431763	DIRECT	Y	OT			29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18431766	DIRECT	Y	OT			90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18432048	DIRECT		HO, LT			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure	Remdesivir			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18432049	DIRECT	Y	DE			71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Pressure Systolic Decreased; Cardiac Arrest; Heart Rate Decreased; Multiple Organ Dysfunction Syndrome; Pulseless Electrical Activity; Retroperitoneal Haemorrhage; Tachypnoea	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency: 200mgx1,100mg/D X4;	Gilead
	Acetaminophen 650 Mg Prn	C			Not Reported
	Albumin Human 5% Ivpb 25 G	C			Not Reported
	Amiodarone 200 Mg	C			Not Reported
	Aspirin 325 Mg	C			Not Reported
	Azithromycin 500 Mg	C			Not Reported
	Ceftriaxone 1 G Iv	C			Not Reported
	Dexamethasone 10 Mg/Ml	C			Not Reported
	Diltiazem 20 Mg	C			Not Reported
	Enoxaparin 80 Mg	C			Not Reported
	Famotidine 20 Mg	C			Not Reported
	Fentanyl 50 Mcg/Ml	C			Not Reported
	Furosemide 20 Mg	C			Not Reported
	Heparin 5000 Units	C			Not Reported
	Hydrocodone-Homatropine 5-1.5 Mg/5 Ml	C			Not Reported
	Zinc Sulfate 220 Mg	C			Not Reported
	Piperacilin-Tazobactam 3.375 G	C			Not Reported
	Loperamide Capsule 2 Mg	C			Not Reported
	Metoprolol Tartrate 25 Mg	C			Not Reported
	Oxycodone 10 Mg	C			Not Reported
	Norepinephrine 8 Mg	C			Not Reported
	Vasopressin 20 Units	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18432051	DIRECT	Y	OT			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18432156	DIRECT	Y	DE			91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Alanine Aminotransferase Increased; Apnoea;	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

Aspartate Aminotransferase Increased; Blood Creatinine Increased; Hypotension; Hypoxia; Rectal Haemorrhage; Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18435204	DIRECT	Y	OT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18435209	DIRECT	Y	DE			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Palliative Care; Renal Impairment	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2020	18435213	DIRECT	Y	OT			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tociluzimab			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Lovenox			C				Not Reported
	Epoprostenol			C				Not Reported
	Solu-Medrol			C				Not Reported
	Cisatracurium			C				Not Reported

	Colchicine			C						Not Reported
	Meropenem			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18044852	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484004		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Maternal Exposure During Pregnancy	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S				Gilead
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18223724	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0492421		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	Remdesivir			S	Unknown	200 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Iopamidol Icu-Vita			C				Not Reported
	Acetaminophen			C				Not Reported
	Etomidate			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Succinylcholine [Suxamethonium Chloride]			C				Not Reported
	Normal Saline			C				Not Reported
	Propofol			C				Not Reported
	Asa			C				Not Reported
	Atorvastatin			C				Not Reported
	Coreg			C				Not Reported
	Dexamethasone			C				Not Reported
	Hydralazine			C				Not Reported
	Humalog			C				Not Reported
	Duoneb			C				Not Reported

			Protonix [Omeprazole]		C					Not Reported
			Miralax		C					Not Reported
			Tamsulosin		C					Not Reported
			Vancomycin		C					Not Reported
			Heparin		C					Not Reported
			Diltiazem		C					Not Reported
			Nitroglycerin		C					Not Reported
			Zofran [Ondansetron Hydrochloride]		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18395835	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0499431		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Alprazolam			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Duloxetine			C				Not Reported
	Enalapril			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Guaifenesin			C				Not Reported
	Hydralazine			C				Not Reported
	Hydrocodone-Acetaminophen			C				Not Reported
	Insulin Aspart			C				Not Reported
	Ipratropium			C				Not Reported

	Levothyroxine	C	Not Reported
	Melatonin	C	Not Reported
	Mupirocin	C	Not Reported
	Norepinephrine	C	Not Reported
	Ondansetron	C	Not Reported
	Piperacillin & Tazobactam	C	Not Reported
	Propofol	C	Not Reported
	Tramadol	C	Not Reported
	Tamsulosin	C	Not Reported
	Vecuronium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18425397	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-053956		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash Maculo-Papular; Therapeutic Response Unexpected	Azithromycin			S	Unknown			Aurobindo
	Dextromethorphan			S	Unknown	Unk		Not Reported
	Lopinavir + Ritonavir			S	Oral			Not Reported
	Interferon Beta			S	Oral			Not Reported
	Ceftriaxone			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remdesivir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18435584	DIRECT	Y	RI			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18435604	DIRECT	Y	RI			81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Chills; Infusion Related Reaction	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18435844	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Myalgia; Rash Maculo-Papular	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18436132	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1842169		5 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Off Label Use; Product Use Issue	Dexamethasone			S	Oral	One Dose		Actavis
	Vincristine			S	Intrathecal			Teva
	Remdesivir			S	Intravenous (not otherwise specified)	Loading Dose 5mg/Kg		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	2.5 Mg/Kg Daily;		Not Reported
	Dexamethasone			S	Intrathecal			Not Reported
	Pegylated Asparaginase			S	Unknown			Not Reported
	Methotrexate			S	Intrathecal			Not Reported
	Adrenaline			C		Nebulised		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18436186	DIRECT	Y	DS, HO, LT			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Cerebrovascular Accident; Respiratory	Remdesivir			S				Not Reported

Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18436202	DIRECT	Y	HO			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Cyanosis; Dyspnoea; Oxygen Saturation Decreased; Respiratory Rate Increased	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18436477	DIRECT	Y	OT			81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
International Normalised Ratio Increased	Remdesivir (Eua)			S	Intravenous (not otherwise specified)			Not Reported
	Apixaban			C				Not Reported
	Dexamethasone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Lisinopril			C				Not Reported
	Prazosin			C				Not Reported
	Tamsulosin			C				Not Reported
	Levofloxacin			C				Not Reported
	Acetaminophen			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Ibuprofen			C				Not Reported
	Ketorolac			C				Not Reported
	Enoxaparin			C				Not Reported
	Vancomycin			C				Not Reported
	Zosyn			C				Not Reported
	Hydromorphone			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18436677	DIRECT	Y	DE			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Condition Aggravated; Dyspnoea; Hypoxia; Pulmonary Embolism; Pulse Absent; Respiratory Arrest; Respiratory Failure	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Ipratropium-Albuterol			C				Not Reported
	Levofloxacin			C				Not Reported
	Vancomycin			C				Not Reported
	Acetylcysteine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Carvedilol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enalapril			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Ivermectin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Montelukast			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439105	EXPEDITED (15-DAY)		HO, OT	NL-GILEAD-2020-0460624		64 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Drug Interaction; Hepatotoxicity; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Chloroquine			S	Unknown	600 Mg Loading Dose		Not Reported
	Rocuronium			C	Intravenous (not	7 Ug		Not Reported

			otherwise specified)		
Midazolam	C	Intravenous (not otherwise specified)	5 Mg		Not Reported
Clonidine	C	Intravenous (not otherwise specified)	1200 Ug		Not Reported
Sufentanil	C	Intravenous (not otherwise specified)	50 Ug		Not Reported
Nadroparin	C	Subcutaneous	Unk		Not Reported
Paracetamol	C	Oral	1000 Mg		Not Reported
Colistin	C	Respiratory (inhalation)	10000 Iu		Not Reported
Orabase Baby	C	Buccal	0.5 Mg		Not Reported
Amlodipine	C	Oral	10 Mg		Not Reported
Atorvastatin	C	Oral	20 Mg		Not Reported
Simvastatin	C		Unk		Not Reported
Cefuroxim [Cefuroxime]	C		Unk		Not Reported
Metoclopramide	C		Unk		Not Reported
Tobramycine [Tobramycin]	C		Unk		Not Reported
Amiodarone	C		700 Mg, Unk		Not Reported
Oxygen	C				Not Reported
Movicolon	C	Oral			Not Reported
Orabase [Dexamethasone]	C	Buccal			Not Reported
Sdd Suspension	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439127	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0501699		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439128	EXPEDITED (15-DAY)		DE, OT	BR-GILEAD-2020-0500094		42 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endotracheal Intubation; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Placebo			S	Intravenous (not otherwise specified)	Unk		Unknown
	Placebo			S	Intravenous (not otherwise specified)	Most Recent Dose Of Blinded Tocilizumab Prior To Adverse Event Onset 08 Oct 2020 At 16:25		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439131	EXPEDITED (15-DAY)		DE, HO, LT, OT	BR-GILEAD-2020-0490082		55 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atelectasis; Pneumonia Klebsiella; Post Procedural Haemorrhage; Respiratory Failure; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)	Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Qd		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	00 Ml) Prior To Onset Of		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439133	EXPEDITED (15-DAY)		DE, LT, OT	BR-GILEAD-2020-0496346		66 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Tocilizumab			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Dexamethasone			C					Not Reported
	Ceftriaxone			C		2 Gtt Drops			Not Reported
	Azithromycin			C		500 Mg			Not Reported
	Enoxaparin			C					Not Reported
	Oseltamivir			C					Not Reported
	Enalapril			C		10 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439139	EXPEDITED (15-DAY)		DE	BR-GILEAD-2020-0496189		61 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	250 Ml		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	250 Ml		Gilead
	Placebo			S	Intravenous (not otherwise specified)	First Dose Of Blinded Tocilizumab Which Also The Most Recent Dose Prior To Ae Onset		Unknown
	Placebo			S	Intravenous (not otherwise specified)	Unk		Unknown
	Furosemida [Furosemide]			C				Not Reported
	Hydralazine			C				Not Reported
	Midazolam			C				Not Reported
	Fentanil			C				Not Reported
	Propofol			C				Not Reported
	Cisatracurium			C				Not Reported
	Norepinefrina [Norepinephrine]			C		4 Ampule		Not Reported
	Norepinefrina [Norepinephrine]			C		4 Ampule		Not Reported
	Dexmedetomidine			C				Not Reported
	Quetiapine			C				Not Reported
	Metadona [Methadone]			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported

		Dexamethasone			C					Not Reported
		Salbutamol			C					Not Reported
		Terbutaline			C					Not Reported
		Ceftriaxone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439142	EXPEDITED (15-DAY)		HO, LT	US-GILEAD-2020-0498852		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Streptococcal Infection	Blinded Interferon Beta-1a			S	Intravenous (not otherwise specified)	100 Mg, Qd		Unknown
	Blinded Placebo			S	Intravenous (not otherwise specified)	100 Mg, Qd		Unknown
	Blinded Interferon Beta-1a			S	Subcutaneous	44 Meq, Qod		Unknown
	Blinded Placebo			S	Subcutaneous	44 Meq, Qod		Unknown
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Metoprolol			C		Unk		Not Reported
	Lisinopril			C		Unk		Not Reported
	Torsemide			C		Unk		Not Reported
	Pravastatin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Aspirin 81			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Insulin Aspart			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Ketamine			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported

Docusate Sodium	C	Unk	Not Reported
Miralax	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Hydromorphone	C	Unk	Not Reported
Insulin Glargine	C	Unk	Not Reported
Sodium Citrate Acid	C	Unk	Not Reported
Meropenem	C	Unk	Not Reported
Fludrocortisone	C	Unk	Not Reported
Hydrocortisone	C	Unk	Not Reported
Vasopressin	C	Unk	Not Reported
Lactulose	C	Unk	Not Reported
Amiodarone	C	Unk	Not Reported
Calcium Chloride	C	Unk	Not Reported
Insulin Regular [Insulin Bovine]	C	Unk	Not Reported
Phenylephrine	C	Unk	Not Reported
Bicarbonate	C	Unk	Not Reported
Calcium	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439148	EXPEDITED (15-DAY)		DE, LT, OT	BR-GILEAD-2020-0495975		20 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Obstructive Shock; Pneumonia; Pneumothorax; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439152	EXPEDITED (15-DAY)		DE, OT	NL-GILEAD-2020-0500895		68 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Lactic Acidosis; Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous (not otherwise specified)	1dd 100 Mg, Infusie		Gilead
	Metoprolol			C		Tablet, 50 Mg (Milligram)		Not Reported
	Sitagliptin			C		Tablet, 25 Mg (Milligram)		Not Reported
	Imatinib			C		400 Mg Tablet Of Placebo		Not Reported
	Paracetamol			C		Tablet, 500 Mg (Milligram)		Not Reported
	Metformin			C		Tablet, 1000 Mg (Milligram)		Not Reported
	Pantoprazole			C		Maagsapresistente Tablet, 20 Mg (Milligram)		Not Reported
	Lisinopril			C		Tablet, 20 Mg (Milligram)		Not Reported
	Dexamethasone			C		Tablet, 1,5 Mg (Milligram)		Not Reported
	Glimepiride			C		Tablet, 3 Mg (Milligram)		Not Reported
	Carbasalaatcalcium Cardio			C		100 Mg		Not Reported
	Insulin Aspart			C		1 Dosage Form		Not Reported
	Nadroparine			C		1 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439610	DIRECT	Y				42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439634	DIRECT	Y				24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Pyrexia; Sinus Bradycardia	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C				Not Reported
	Zinc Sulfate			C				Not Reported

		Iohexol (8/1 At 2022)			C					Not Reported
		Suboxone			C					Not Reported
		Ceftriaxone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439883	DIRECT	Y				75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin 500 Mg Iv Qd			C				Not Reported
	Ceftriaxone 2000 Mg Iv Daily			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439891	DIRECT	Y	OT			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Pressure Diastolic Decreased; Blood Pressure Systolic Decreased	Remdesivir	Y		S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439899	DIRECT	Y				72 YR	Male	GUM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:One Time Order;		Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2020	18439959	DIRECT	Y				49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspnoea	Remdesivir			S	Intravenous (not otherwise specified)	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2020	18408022	EXPEDITED (15-DAY)			US-GILEAD-2020-0500136		86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Dose Omission; Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2020	18439992	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-206539		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Off Label Use; Pruritus; Rash Maculo-Papular	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Interferon Beta			S				Not Reported
	Azithromycin			S				Not Reported
	Tocilizumab			S				Not Reported
	Dextromethorphan			S				Not Reported
	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2020	18441009	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020418268		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Covid-19 Pneumonia; Respiratory Failure	Atorvastatin Calcium			S	Oral	Unk		Pfizer
	Veklury			S	Intravenous (not otherwise specified)	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2020	18441168	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Therapy Cessation	Remdesivir	Y		S	Intravenous drip			Gilead
	Albuterol			C				Not Reported
	Augmentin 875-125mg			C				Not Reported
	Azithromycin 500mg			C				Not Reported
	Ceftriaxone 1000mg			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Hepairn 5000 Unit			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2020	18441366	DIRECT	Y	OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Swelling; Rash	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2020	18441491	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Albumin Increased; Blood Alkaline Phosphatase Increased; Blood Bicarbonate Decreased; Blood Gases Abnormal; Dialysis;	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Cefepime 1gm Iv Q12hr			C				Not Reported
	Azithromycin 500mg Iv Once Then Po Once			C				Not Reported
	Ceftriaxone 1gm Iv Once			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Famotidine 20mg Po Daily			C				Not Reported
	Meropenem Renally Dosed			C				Not Reported
	Methylprednisolone 40mg Iv			C				Not Reported

Encephalopathy; Haematocrit Decreased; Haemoglobin Decreased; Pao2/Fio2 Ratio Decreased; Protein Total Decreased; Red Cell Distribution Width Increased; Renal Impairment; White Blood Cell Count Increased	Q12hr			
	Metronidazole 500mg Iv Q8hr	C		Not Reported
	Micafungin 100mg Iv Daily	C		Not Reported
	Pantoprazole 40mg Po Bedtime	C		Not Reported
	Vancomycin Iv Per Protocol	C		Not Reported
	Vancomycin 500mg Po Q6hr	C		Not Reported
	Zinc Sulfate 220mg Po Bid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18084128	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486098		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Norco			C		7 Doses		Not Reported
	Norco			C	Other	1 Tab, Q4h, Prn		Not Reported
	Acetaminophen			C		500 Mg, 2 Doses		Not Reported
	Acetaminophen			C	Other	500 Mg, Q8h, Prn		Not Reported
	Oxygen			C				Not Reported
	K-Dur			C	Oral	40 Meq, Once		Not Reported
	K-Dur			C	Oral	40 Meq, Once		Not Reported
	Magnesium Sulfate			C	Intravenous (not otherwise specified)	100 Ml, Once		Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	30 Ml, Qd		Not Reported
	Sodium Chloride			C	Intravenous (not otherwise specified)	1000 Ml, Q12h3m		Not Reported
	Lidoderm			C	Topical	1 Each, Qd		Not Reported
	Protonix [Omeprazole]			C	Intravenous (not otherwise specified)	40 Mg, Bid		Not Reported

	Protonix [Omeprazole]	C	Oral	40 Mg, Qd	Not Reported
	Levaquin	C	Intravenous (not otherwise specified)	750 Mg In 150 Ml Nacl, Qd	Not Reported
	Levaquin	C	Oral	750 Mg, Qd	Not Reported
	Levaquin	C	Intravenous (not otherwise specified)	150 Ml, Qd	Not Reported
	Decadron [Dexamethasone]	C	Intravenous (not otherwise specified)	6 Mg, Qd	Not Reported
	Decadron [Dexamethasone]	C	Oral	6 Mg, Qd	Not Reported
	Lovenox [Enoxaparin Sodium]	C	Subcutaneous	40 Mg, Qd	Not Reported
	Zofran [Ondansetron Hydrochloride]	C	Intravenous (not otherwise specified)	4 Mg, Q4h, Prn	Not Reported
	Rocephin [Ceftriaxone Sodium]	C	Intravenous (not otherwise specified)	1 G	Not Reported
	Zithromax	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Tylenol Extra Strength	C	Other	1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18089362	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0486238		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Covid-19; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Rocephin			C		Unk		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G		Not Reported

	Lovenox [Levofloxacin]			C	Subcutaneous	40 Mg			Not Reported
	Fentanyl			C					Not Reported
	Propofol			C					Not Reported
	Versed			C					Not Reported
	Phenylephrine			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18439129	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0501671			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased	Blinded Interferon Beta-1a			S	Subcutaneous	Unk		Unknown
	Blinded Placebo			S	Subcutaneous	Unk		Unknown
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18439155	EXPEDITED (15-DAY)		DE, HO, LT, OT	BR-GILEAD-2020-0500020		54 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Covid-19 Pneumonia; Hypernatraemia; Opportunistic Infection; Pneumonia; Urinary Tract Infection	Remdesivir			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose Of Blinded Tocilizumab Prior To Ae Onset 03/Oct/2020 At 11:30 Hours		Gilead
	Placebo			S	Intravenous (not otherwise specified)	Unk		Unknown
	Placebo			S	Intravenous (not otherwise specified)	Unk		Unknown
	Ceftriaxone			C				Not Reported
	Azitromicina			C				Not Reported
	Omeprazole			C				Not Reported
	Enoxaparina			C				Not Reported
	Dipirone			C				Not Reported
	Metoclopramide			C				Not Reported
	Methylprednisolone			C				Not Reported

	Precedex			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18445862	DIRECT	Y				33 YR	Female	GUM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Pantoprazole			C				Not Reported
	Enoxaparin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Thiamine			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18446712	DIRECT	Y				81 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18446772	DIRECT	Y				86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18447117	DIRECT	Y	OT			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Hepatic Failure; Hypoxia; Ischaemic Hepatitis; Liver Injury; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Amiodarone			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Carvedilol			C				Not Reported
	Cefepime			C				Not Reported
	Citalopram			C				Not Reported
	Dexamethasone			C				Not Reported
	Digoxin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Hydromorphone			C				Not Reported
	Prasugrel			C				Not Reported
	Thyroid Desiccated			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18447684	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0482412		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Angioedema; Aspartate Aminotransferase Increased; Covid-19; Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Propofol			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Acetaminophen			C		Unk		Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)			Not Reported
	Ibuprofen			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18447704	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0502174		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Covid-19; Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Once		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Once		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Famotidine			C	Oral	20 Mg, Qd		Not Reported
	Meropenem			C		Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Mg, Bid		Not Reported
	Metronidazole			C	Intravenous (not otherwise specified)	500 Mg, Q8h		Not Reported
	Micafungin			C	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Vancomycin			C	Oral	500 Mg, Q6h		Not Reported
	Zinc Sulphate			C	Oral	220 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18448113	EXPEDITED (15-DAY)		HO, OT	ES-GILEAD-2020-0500888			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Foetal Growth Abnormality; Hypoglycaemia	Remdesivir	S	Transplacental	Unk	Gilead
	Ceftriaxone	C		Unk	Not Reported
	Hydroxychloroquine	C		Unk	Not Reported
	Lopinavir + Ritonavir	C		Unk	Not Reported
	Metilprednisolone	C		Unk	Not Reported
	Metilprednisolone	C		Unk	Not Reported
	Yodocefol	C			Not Reported
	Famotidine	C			Not Reported
	Cariban [Doxylamine Succinate; Pyridoxine Hydrochloride]	C			Not Reported
	Misoprostol	C			Not Reported
	Oxytocin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18448346	EXPEDITED (15-DAY)		HO, LT, OT	JP-GILEAD-2020-0496567		71 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory; Laryngeal Oedema; Oxygen Saturation Abnormal	Remdesivir			S	Intravenous drip	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Olmetec			S	Oral	20 Mg, Qd		Not Reported
	Olmetec			S	Oral	20 Mg, Qd		Not Reported
	Lactec			C	Intravenous drip	1000 Ml, Tid		Not Reported
	Lactec			C	Intravenous drip	1000 Ml, Bid		Not Reported
	Heparin Calcium			C	Subcutaneous	5000 Iu, Qd		Not Reported
	Heparin Calcium			C	Subcutaneous	5000 Iu, Bid		Not Reported
	Heparin Calcium			C	Subcutaneous	5000 Iu, Bid		Not Reported
	Kcl Corrective			C	Intravenous drip	100 Ml, Bid		Not Reported
	Sodium Phosphate			C	Intravenous drip	20 Ml, Qd		Not Reported
	Magnesium Sulfate			C	Intravenous drip	20 Ml, Qd		Not Reported
	Magnesium Sulfate			C	Intravenous drip	20 Ml, Qd		Not Reported
	Dexart			C	Intravenous (not	6.6 Mg, Qd		Not Reported

		otherwise specified)		
Ketalar	C	Intravenous (not otherwise specified)	200 Mg, Qd	Not Reported
Propofol	C	Intravenous (not otherwise specified)	20 Ml, Qd	Not Reported
Propofol	C	Intravenous drip	Unk	Not Reported
Propofol	C	Intravenous drip	50 Ml, Tid	Not Reported
Eslax	C	Intravenous (not otherwise specified)	50 Mg, Qd	Not Reported
Neo Synesin	C	Intravenous (not otherwise specified)	1 Mg, Qd	Not Reported
Isotonic Sodium Chloride Solution	C	Intravenous drip	250 Ml, Tid	Not Reported
Fentanyl	C	Intravenous drip	10 Ml, Bid	Not Reported
Fentanyl	C	Intravenous drip	10 Ml, Qd	Not Reported
Noradrenaline (Norpinephrine)	C	Intravenous drip	6 Mg, Bid	Not Reported
Noradrenaline (Norpinephrine)	C	Intravenous drip	6 Mg, Tid	Not Reported
Heparin Sodium	C	Intravenous drip	10000 Iu, Qd	Not Reported
Heparin Sodium	C	Intravenous drip	10000 Iu, Bid	Not Reported
Humulin R	C	Intravenous drip	50 Iu, Qd	Not Reported
Nicardipine Hydrochloride	C	Intravenous drip	50 Mg, Qd	Not Reported
Nicardipine Hydrochloride	C	Intravenous drip	Unk Unk, Bid	Not Reported
Nicardipine Hydrochloride	C	Intravenous drip	50 Mg, Bid	Not Reported
Lansoprazole	C	Oral	15 Mg, Qd	Not Reported
Lansoprazole	C	Oral	15 Mg, Qd	Not Reported
Potassium Chloride	C	Oral	2 G, Prn	Not Reported
Potassium Chloride	C	Oral	2 G, Prn	Not Reported
Magmitt	C	Other	330 Mg, Tid	Not Reported
Magmitt	C	Oral	330 Mg, Tid	Not Reported
Amlodin	C	Oral	2.5 Mg, Prn	Not Reported
Amlodin	C	Oral	2.5 Mg, Qd	Not Reported

Amlodin	C	Oral	5 Mg, Qd		Not Reported
Decadron A	C	Oral	6 Mg, Qd		Not Reported
Sennoside A	C	Oral	36 Mg, Qd		Not Reported
Sp Troches	C	Oropharingeal	0.25 Mg, Prn		Not Reported
Triazolam	C	Oral	0.25 Mg, Qd		Not Reported
Calonal	C	Oral	500 Mg, Qid		Not Reported
Sodium Chloride	C	Oral	1 G, Tid		Not Reported
Sodium Picosulfate	C	Oral	15 Gtt Drops, Qd		Not Reported
Amlodine [Amlodipine]	C		5 Mg, Qd		Not Reported
Takepron	C		15 Mg, Qd		Not Reported
Mucosta	C		100 Mg, Tid		Not Reported
Depas [Etizolam]	C		0.5 Mg, Tid		Not Reported
Halcion	C		0.25 Mg, Tid		Not Reported
Livalo	C		1 Mg, Tid		Not Reported
Pursennide [Sennoside A+B]	C		36 Mg, Qd		Not Reported
Mohrus	C	Other	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18449848	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0492719		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bacteraemia; Bacteraemia; Sepsis; Urinary Tract Infection	Remdesivir			S	Intravenous (not otherwise specified)	Rdv Loading Dose And A Once-Daily Maintenance Dose Of Remdesivir From Days 2-10		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	On 03/Aug/2020, Received Most Recent Dose Prior To Sae Onset		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	Followed By One Infusion Of Tcz On Day 1		Not Reported
	Tocilizumab			S	Intravenous (not	On The Same Date,		Not Reported

				otherwise specified)	Received Most Recent Dose Medication	
	Cefepime		C			Not Reported
	Esomeprazole		C		20 Mg	Not Reported
	Ondansetron		C		Prn	Not Reported
	Ondansetron		C			Not Reported
	Lopressor		C		Prn	Not Reported
	Insulin		C		50 Units Other	Not Reported
	Lovenox [Enoxaparin Sodium]		C		Other	Not Reported
	Atorvastatin		C		40 Mg	Not Reported
	Acetaminophen		C		Prn	Not Reported
	Propofol		C		0.418	Not Reported
	Oxygen		C			Not Reported
	Voriconazole		C		480 Mg	Not Reported
	Voriconazole		C		320 Mg	Not Reported
	Sildenafil		C		20 Mg	Not Reported
	Chlorhexidine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18449857	EXPEDITED (15-DAY)		LT, OT	BR-GILEAD-2020-0490348		61 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endotracheal Intubation Complication; Pneumonia; Sepsis; Systemic Candida; Tracheobronchitis	Remdesivir			S	Intravenous (not otherwise specified)	Most Recent Dose Of Remdesivir Prior To Sae Onset: 09/Aug/2020 At 13:05 Hr		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Most Recent Dose Of Remdesivir Prior To Sae Onset: 17/Aug/2020 At 15:07 Hr		Gilead
	Placebo			S	Intravenous (not otherwise specified)	Most Recent Dose Of Blinded Tocilizumab Prior To Sae/Ae Onset: 09/Aug/2020 At 09:42 Hr		Unknown

	Placebo	S	Intravenous (not otherwise specified)	Unk	Unknown
	Ceftriaxone	C			Not Reported
	Azithromicin	C		500 Mg	Not Reported
	Oseltamivir	C		75 Mg	Not Reported
	Oseltamivir	C			Not Reported
	Omeprazole	C		20 Mg	Not Reported
	Dipirone	C		1000 Mg	Not Reported
	Enoxaparin	C		40 Mg	Not Reported
	Plasil [Metoclopramide]	C		5 Mg	Not Reported
	Dexamethasone	C		6 Mg	Not Reported
	Precedex	C		100 Ug	Not Reported
	Losartan	C		50 Mg	Not Reported
	Simvastatin	C		40 Mg	Not Reported
	Mirtazapine	C			Not Reported
	Alenia [Budesonide;Formoterol Fumarate]	C			Not Reported
	Glucose	C		5 Ampule	Not Reported
	Insulin, Regular	C		10 Iu	Not Reported
	Insulin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18450444	EXPEDITED (15-DAY)		OT	FR-GILEAD-2020-0499730		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Claforan [Cefotaxime Sodium]			C	Intravenous (not otherwise specified)	2 G		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous	9000 Iu, Bid		Not Reported

	Oxygen			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18450446	EXPEDITED (15-DAY)		DE, LT, OT	BR-GILEAD-2020-0498785		63 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pneumonia Acinetobacter	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C		1 G		Not Reported
	Omeprazole			C		40 Mg		Not Reported
	Methylprednisolon [Methylprednisolone]			C		62.5 Mg		Not Reported
	Hydrocortisone			C		200 Mg		Not Reported
	Dexamethasone			C		6 Mg		Not Reported
	Enoxaparin			C		6 Mg		Not Reported
	Losartan			C		50 Mg		Not Reported
	Simvastatin			C		20 Mg		Not Reported
	Levothyroxine			C				Not Reported
	Cisatracurio			C		2 Mg		Not Reported
	Cisatracurio			C	Intravenous drip	20 Ml		Not Reported
	Etomidate			C		20 Mg		Not Reported
	Fentanyl			C				Not Reported
	Fentanyl			C	Intravenous drip	60 Ml		Not Reported
	Midazolam			C	Intravenous drip	60 Ml		Not Reported
	Noradrenaline [Norepinephrine]			C	Intravenous drip	20 Ml		Not Reported
	Vasopressin			C	Intravenous drip			Not Reported
	Hypromellose			C				Not Reported
	Bromopride			C				Not Reported
	Ketamine			C				Not Reported
	Blood Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18450913	EXPEDITED (15-DAY)		HO	PT-GILEAD-2020-0499755		40 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Veklury			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Veklury			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			S	Intravenous (not otherwise specified)	6 Mg, Unk		Not Reported
	Salbutamol			C	Respiratory (inhalation)	100 Mg, Unk		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	20 Mg, Unk		Not Reported
	Metamizole Magnesium			C	Oral	575 Mg, Unk		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Calcium Carbonate			C	Oral	1500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18450919	EXPEDITED (15-DAY)		HO, OT	FR-GILEAD-2020-0500366			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2020	18451040	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0502269		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Veklury			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Veklury			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2020	18448112	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-054872		90 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Agitation	Levofloxacin			S	Intravenous (not otherwise specified)			Aurobindo
	Omeprazole			S	Intravenous (not otherwise specified)	1 Ampolla Diaria		Aurobindo
	Azithromycin 500 Mg Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Clexane			S	Subcutaneous	1-0-0		Not Reported
	Seguril			S	Oral	1-0-0		Not Reported
	Dexametason			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200/Mg El Primer Día Y 100 Mg Los Restante 4 Días		Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2020	18451639	DIRECT	Y	OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Albuterol Inhalation			C				Not Reported

		Amlodipine			C						Not Reported
		Atorvastatin			C						Not Reported
		Dexamethasone			C						Not Reported
		Doxycycline			C						Not Reported
		Famotidine			C						Not Reported
		Folic Acid			C						Not Reported
		Guaifenesin			C						Not Reported
		Ipratropium Inhalation			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2020	18339040	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0497200		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Sodium Chloride			C				Not Reported
	Epinephrine			C				Not Reported
	Calcium Chloride			C				Not Reported
	Flucelvax Tetra			C				Not Reported
	Ramelteon			C				Not Reported
	Olanzapine			C				Not Reported
	Quetiapine			C				Not Reported
	Bisacodyl			C				Not Reported
	Plasma-Lyte A			C				Not Reported
	Cefepime			C				Not Reported
	Acetaminophen			C				Not Reported
	Famotidine			C				Not Reported
	Dexmedetomidin			C				Not Reported
	Methocarbamol			C				Not Reported
	Lidocaine Hcl			C				Not Reported
	Senokot S			C				Not Reported
	Miralax			C				Not Reported
	Enoxaparin Sodium			C				Not Reported
	Mupirocin			C				Not Reported
	Gabapentin			C				Not Reported
	Norepinephrine			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported

	Dexamethasone	C	Not Reported
	Potassium Phosphate Dibasic	C	Not Reported
	Dextrose	C	Not Reported
	Potassium Chloride	C	Not Reported
	Magnesium Sulfate	C	Not Reported
	Oxycodone Hcl	C	Not Reported
	Cisatracurium	C	Not Reported
	Midazolam Hcl	C	Not Reported
	Insulin Human	C	Not Reported
	Glucagon	C	Not Reported
	Metoprolol Tartrate	C	Not Reported
	Fentanyl Citrate	C	Not Reported
	Diphtheria	C	Not Reported
	Ancef [Cefazolin Sodium]	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2020	18352375	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0497541		88 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Fibrin D Dimer Increased; Leukopenia; Thrombocytopenia	Remdesivir			S	Unknown	Unk		Gilead
	Remdesivir			S	Unknown	Unk		Gilead
	Remdesivir			S	Unknown	Unk		Gilead
	Alfuzosin			C	Oral	10 Mg, Qd		Not Reported
	Aspirin (E.C.)			C	Oral	81 Mg, Qd		Not Reported
	Lipitor [Atorvastatin]			C	Oral	80 Mg, Qd		Not Reported
	Plavix			C	Oral	75 Mg, Qd		Not Reported
	Folic Acid			C	Oral	1 Mg, Qd		Not Reported
	Heparin			C	Subcutaneous	5000 Units		Not Reported
	Magnesium Sulfate			C	Intravenous (not otherwise specified)	1 G, Q1hr		Not Reported
	Melatonin			C	Oral	3 Mg		Not Reported
	Toprol Xl			C	Oral	50 Mg, Qd		Not Reported
	Multivitamin [Vitamins Nos]			C	Oral	1 Dosage Form, Qd		Not Reported
	Kcl			C	Oral	30 Meq, Bid		Not Reported

	Seroquel	C				Not Reported
	Flomax [Tamsulosin Hydrochloride]	C				Not Reported
	Thiamine	C	Oral	100 Mg, Qd		Not Reported
	Tylenol	C	Oral	975 Mg		Not Reported
	Norvasc	C	Oral	10 Mg, Qd		Not Reported
	Dextrose	C	Intravenous (not otherwise specified)	12.5 G		Not Reported
	Dextrose	C	Intravenous (not otherwise specified)	25 Unk		Not Reported
	Lactated Ringers	C	Intravenous (not otherwise specified)	125 Ml/Hr		Not Reported
	Insulin Lispro	C	Subcutaneous	2-10 Units, Q6h		Not Reported
	Potassium Phosphate [Potassium Phosphate Dibasic]	C	Intravenous (not otherwise specified)	15 Mmol		Not Reported
	Sodium Chloride	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2020	18372548	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0498117		92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Sinus Node Dysfunction	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Lantus			C				Not Reported
	Synthroid			C				Not Reported
	Amlodipine			C		Unk		Not Reported
	Diclofenac			C	Topical	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Furosemide			C				Not Reported
	Glipizide			C				Not Reported
	Hyoscyamine			C		Unk		Not Reported
	Methotrexate			C				Not Reported

Omeprazole	C			Not Reported
Prolia	C			Not Reported
Fiber	C			Not Reported
Systane	C	Ophthalmic		Not Reported
Calcium	C			Not Reported
Docusate Sodium	C			Not Reported
Vitamin B12 [Vitamin B12 Nos]	C			Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Dexamethasone	C		Unk	Not Reported
Albuterol [Salbutamol]	C		Unk	Not Reported
Heparin	C		Unk	Not Reported
Potassium Chloride	C		Unk	Not Reported
Doxycycline	C		Unk	Not Reported
Enoxaparin	C		Unk	Not Reported
Insulin Detemir	C		Unk	Not Reported
Insulin Aspart	C		Unk	Not Reported
Melatonin	C		Unk	Not Reported
Ceftriaxone	C		Unk	Not Reported
Famotidine	C		Unk	Not Reported
Levothyroxine	C		Unk	Not Reported
Calcium Carbonate	C		Unk	Not Reported
Losartan	C		Unk	Not Reported
Vancomycin	C		Unk	Not Reported
Senna Acutifolia	C		Unk	Not Reported
Acetaminophen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2020	18406101	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0500006		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19; Death	Remdesivir			S	Intravenous (not	200 Mg, Once		Gilead

		otherwise specified)		
Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
Eliquis	C			Not Reported
Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg	Not Reported
Lasix [Furosemide]	C			Not Reported
Oxygen	C			Not Reported
Acetaminophen	C	Oral	650 Mg	Not Reported
Albuterol [Salbutamol]	C	Respiratory (inhalation)	Unk	Not Reported
Apixaban	C	Oral	5 Mg	Not Reported
Ascorbic Acid	C	Oral	500 Mg	Not Reported
Azithromycin	C	Oral	500 Mg	Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)	1 G	Not Reported
Digoxin	C	Oral	125 Mcg	Not Reported
Diphenhydramine	C	Oral	25 Mg	Not Reported
Ferrous Sulfate	C	Oral	325 Mcg	Not Reported
Fluocinonide	C	Topical	15 Mg	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
Lorazepam	C	Intravenous (not otherwise specified)	0.5 Mg	Not Reported
Lorazepam	C	Oral	1 Mg	Not Reported
Melatonin	C	Oral	6 Mg	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	125 Mg	Not Reported
Metoprolol	C	Oral	25 Mg	Not Reported
Metoprolol	C	Oral	50 Mg	Not Reported
Mirtazapine	C	Oral	7.5 Mg	Not Reported
Morphine	C	Intravenous (not	0.5 Mg	Not Reported

			otherwise specified)		
	Morphine	C	Intravenous (not otherwise specified)	15 Mg	Not Reported
	Morphine	C	Intravenous (not otherwise specified)	2 Mg	Not Reported
	Ondasetron [Ondansetron]	C			Not Reported
	Ondasetron [Ondansetron]	C			Not Reported
	Pantoprazole	C	Oral	40 Mg	Not Reported
	Piperacillin / Tazobactam	C	Intravenous (not otherwise specified)	3.375 Mg	Not Reported
	Saccharomyces Boulardii Lyophylized	C	Oral	250 Mg	Not Reported
	Scopolamine [Hyoscine]	C	Topical	1.5 Mg	Not Reported
	Tramadol	C	Oral	50 Mg	Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	1 G	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2020	18453224	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0502308		90 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Veklury			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2020	18454262	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0502189		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Death; Pulmonary Embolism; Respiratory Arrest; Respiratory Failure	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported

Albuterol;Ipratropium	C	Unk	Not Reported
Levofloxacin	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported
Acetylcysteine	C	Unk	Not Reported
Ascorbic Acid	C	Unk	Not Reported
Aspirin (E.C.)	C	Unk	Not Reported
Atorvastatin	C	Unk	Not Reported
Carvedilol	C	Unk	Not Reported
Ceftriaxone	C	Unk	Not Reported
Enalapril	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Gabapentin	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Insulin	C	Unk	Not Reported
Isosorbide Mononitrate	C	Unk	Not Reported
Ivermectin	C	Unk	Not Reported
Methylprednisolone	C	Unk	Not Reported
Montelukast	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Dopamine	C		Not Reported
Epinephrine	C		Not Reported
Leucovorine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2020	18454470	EXPEDITED (15-DAY)		LT	BR-GILEAD-2020-0492488		46 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Dipyrone	S	Unknown	Not Reported
Dexmedetomidine	C		Not Reported
Propofol	C		Not Reported
Fentanyl	C		Not Reported
Enoxaparin	C		Not Reported
Dexamethasone	C		Not Reported